IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and)
GLOBAL LIFE SCIENCES	
SOLUTIONS USA, LLC,)
)
Plaintiffs,	Redacted: Public Version
v.) C.A. No. 18-1899-CFC-SRF
)
BIO-RAD LABORATORIES, INC.,) CONSOLIDATED
)
Defendant.)

DECLARATION OF AMY L. DEWITT IN SUPPORT OF PLAINTIFFS'
MOTION TO EXCLUDE EXPERT OPINIONS OF DR. BRUCE GALE
AND IN SUPPORT OF ITS MOTION TO EXCLUDE EXPERT
OPINIONS OF DR. THOMAS KEARL

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC.,

Defendant.

C.A. No. 1:18-cv-01899-CFC

HIGHLT CONFIDENTIAL-FILED UNDER SEAL

DECLARATION OF AMY L. DEWITT IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE EXPERT OPINIONS OF DR. BRUCE GALE AND IN SUPPORT OF ITS MOTION TO EXCLUDE EXPERT OPINIONS OF DR. THOMAS KEARL

- I, Amy L. DeWitt, declare and state as follows:
- 1. I am an attorney at Arnold & Porter LLP and am licensed to practice law in Washington, District of Columbia. I am admitted *pro hac vice* to this Court. I am counsel for Plaintiffs Cytiva Sweden AB and Global Life Sciences Solutions USA LLC (collectively, "Plaintiffs") in the above-captioned matter. I have personal knowledge of the facts set forth and if called to testify, I could and would testify competently thereto.

- 2. Attached hereto as Exhibit 1 is a true and correct copy of excerpts from the November 25, 2020 deposition transcript of Dr. Bruce Gale.
- 3. Attached hereto as Exhibit 2 is a true and correct copy of excerpts from the October 21, 2020 rebuttal expert report of Dr. Bruce Gale.
- 4. Attached hereto as Exhibit 3 is a true and correct copy of excerpts from the May 14, 2020 *Markman* hearing held in the above-captioned matter.
- 5. Attached hereto as Exhibit 4 is a true and correct copy of excerpts from the September 14, 2020 opening expert report of Dr. Bruce Gale.
- 6. Attached hereto as Exhibit 5 is a true and correct copy of excerpts from the August 10, 2015 deposition transcript of Thomas Koshy.
- 7. Attached hereto as Exhibit 6 is a true and correct copy of excerpts from the November 11, 2020 reply expert report of Dr. Bruce Gale.
- 8. Attached hereto as Exhibit 7 is a true and correct copy of excerpts from the November 18, 2020 deposition transcript of Kevin Petersen.
- 9. Attached hereto as Exhibit 8 is a true and correct copy of excerpts from a document Bio-Rad produced in this litigation bearing the Bates number BRGEDEL403802-826.
- 10. Attached hereto as Exhibit 9 is a true and correct copy of excerpts from a document Bio-Rad produced in this litigation bearing the Bates number BRGEDEL100355-368.

- 11. Attached hereto as Exhibit 10 is a true and correct copy of excerpts from the October 21, 2020 rebuttal expert report of Dr. Thomas Kearl.
- 12. Attached hereto as Exhibit 11 is a true and correct copy of excerpts from the November 23, 2020 deposition transcript of Dr. Thomas Kearl.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 15, 2020 in Washington, DC.

Amy L. DeWitt

1s/ My Delltt

CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that on December 15, 2020, this document was served on the persons listed below in the manner indicated:

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EXHIBIT 1 FILED UNDER SEAL

Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. Highly Confidential Bruce Gale, Ph.D.

	Page 1		Page 3
	IN THE UNITED STATES DISTRICT COURT	1	APPEARANCES
	FOR THE DISTRICT OF DELAWARE	2 3	(Via Zoom Videoconferencing
	Cytiva Sweden AB and Global Life	4	ON BEHALF OF PLAINTIFF: CYTIVA SWEDEN AB AND GLOBAL
	Sciences Solutions USA, LLC,		LIFE SCIENCES SOLUTIONS USA, LLC:
	Plaintiff, Case No.	5	Jennifer Sklenar, Esquire
	18-1899-CFC	6	Arnold & Porter Kaye Scholer LLP
	-against- Bio-Rad Laboratories, Inc.,		601 Massachusetts Ave, NW Washington, D.C. 20001-3743
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	HIGHLY CONFIDENTIAL VIDEO-RECORDED DEPOSITION OF	10	ON BEHALF OF DEFENDANT: BIO-RAD LABORATORIES, INC.: Sean Damon, Esquire
	DR. BRUCE GALE	11	Quinn Emanuel Urquhart & Sullivan, LLP
	Zoom Videoconference		1300 I Street NW
	11/25/2020	12	#900
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		14	
	REPORTED BY: AMANDA GORRONO, CLR	15	
	CLR NO. 052005-01	16	ALSO PRESENT:
		17 18	Brian Cannon, Esquire, on behalf of Bio-Rad, Quinn Emanuel Urquhart & Sullivan, LLP
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4	VIDEO-RECORDED DEPOSITION OF DR. BRUCE GALE,	4	DR. BRUCE GALE MS. SKLENAR 7
5	held virtually via Zoom Videoconferencing, before	5	
6	Amanda Gorrono, Certified Live Note Reporter, and	6	EXHIBITS
7	Notary Public of the State of New York.	7	DANIBITS
8	Trought of the state of New York.	8	EXHIBIT DESCRIPTION PAGE
9		9	
10		10	Exhibit 326 Dr. Gale's Opening Report 81
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20		20	Laboratories' Petition for
21		21	Institution of an IPR on US
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Bruce Gale, Ph.D.

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- Sure. I mean, you distinguish different types of chromatography by the type of material or the, I guess, the interactions that occur in the chromatography experiment.
- So what specific components are needed to do ion chromatography that you wouldn't need to do other types of liquid chromatography?
 - Well, the only thing that would be different is the type of column.
 - Q. That's the only difference?
- A. Yes.
- 12 Okay. The electric field flow Q.
- 13 fractionation techniques that you described, that you
- 14 have experiments with, is that a type of liquid 15
- chromatography? 16
 - A. Yes.
- 17 Q. Are there types of chromatography you 18 have experience with that you wouldn't consider to be
- 19 liquid chromatography?
- 21 chromatography, and there may be some other nonliquid
- 22 types of chromatography. But there's -- there's

I mean, there's like gas

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- yourself to be an expert in ion chromatography,
- 2 right? 3

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- I mean, I'm familiar with ion chromatography, but as noted, I'm -- I haven't ever done it before, so I wouldn't say I'm a specific expert in that particular forum.
- So you're not -- you wouldn't say you're specifically an expert in ion chromatography, correct?
 - A. I generally have expertise in chromatography as a field.
 - But not ion chromatography?
- A. I said, I have a general understanding of ion chromatography. I haven't done it before.
 - Okay. So I want to ask you -- just, if I -- if I restrict the questioning to the last 12 years, okay? So since 2008, have you personally performed liquid chromatography since 2008?
 - A.
- 21 Q. And on what machines did you do that?
 - I mean, we -- as I noted, we

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- 1 literally thousands of types of liquid
- 2 chromatography.
 - But in terms of my question, is there any type of chromatography you have experience with that you would not consider it to be liquid
- chromatography?
 - MR. DAMON: Objection to the form.
- I mean, the chromatography 9 experiments that I do are liquid chromatography. I 10 only do fluid flow stuff, so I guess the answer is 11 no
 - Okay. Do you know what the term "Karl Fischer titration" means?
 - Yeah, I have a general sense of what A. it means.
 - Q. Are you a -- have you ever performed a Karl Fischer titration?
 - A. I have not.
 - So you would not consider yourself to be a expert in Karl Fischer titrations; is that fair?
 - That's fair.
 - Q. And similarly, you wouldn't consider

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- primarily do electrical field flow fractionation. We
- 2 build our own instruments. I've done -- not all the
- 3 time, but I regularly work with my students and do
- 4 liquid chromatography in these electrical field flow
 - fractionation instruments.
 - So have you done liquid Q. chromatography personally over the last 20 -- or 12 years on -- on any systems other than electrical
- 9 field flow fractionation systems? 10
 - Well, other than the Applikon instrument, we -- I worked with Kevin and Travis to set that up to do chromatography.
 - Well, we're going to come back to that. Anything else over the last 12 years, other than --
 - A. Well, I've done electrophoresis -- or I helped build an EKKC. I'm trying to remember what the acronym is for. Electrokinetic -- I can't remember what the second K is for. But it's a version of, we'll call it, electrophoresis and electrical field flow fractionation, kind of
- 22 combined.

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Bruce Gale, Ph.D.

Page 29 Page 31 Have you ever performed liquid like that. 2 chromatography using an NGC system? 2 You said "I would assume that it O. 3 A. I have not personally done that. means," and then you gave a list. Is there a reason 4 4 that you are assuming what it means rather than Have you ever been present where 5 anyone else had performed liquid chromatography using knowing what it means? 6 an NGC system? A. Well, that's my interpretation. A. I have. There's not a difference. В Q. When was that? And have -- where is your 9 I don't remember the exact date, it understanding about what it means to modify a fluid 10 10 was 2015 probably. flow path -- where does is that understanding come 11 11 Okay. So it's been about five years from? 12 12 since you've seen anyone perform liquid MR. DAMON: Objection to form. 13 13 chromatography using an NGC system? That would come from, you know, my 14 14 A. That's correct. personal experience in using chromatography systems 15 15 And have you ever performed liquid and, I mean, the documents that I've seen in the 16 16 chromatography using an ÄKTA system? specification and in this case. 17 17 Have you personally modified the 18 Have you ever been present when 18 fluid flow path of a liquid chromatography system? 19

Page 30

was -- when I saw it. 2

ÄKTA system?

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Q. So you don't know one way or another whether you've ever witnessed anyone performing liquid chromatography with an ÄKTA system?

anyone has performed liquid chromatography using an

I've seen an ÄKTA system. I can't

remember if they were doing chromatography when it

A. That's correct.

What is -- are you familiar with the term fluid flow path as it relates to liquid chromatography?

A. Sure.

> Q. What is a fluid flow path?

That's the -- well, it's the trail or the, you know, the physical location of where fluid moves when chromatography is being performed.

And what does it mean to modify the fluid flow path of a liquid chromatography system?

A. I would assume that that means you just change something in the flow path. It could be change the connection, change the length of a tube, change the sequence of how, you know, components in the liquid chromatography system are connected. I mean, it may even be just bending a tube to, you know, put it into a -- a different shape or something

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1 flow path. We put connections in or out, maybe 2 change the sample lube, put in a different pump. You 3 know, I don't do it every day, but probably every few months I'll -- I'll do something like that. 5 What is PCR? Q. A. Polymerase chain reaction. 7

When was that?

I mean, every time we do

chromatography experiments, we usually adjust the

Q. What direct experience do you with

PCR?

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A.

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A.

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I mean, I've -- I've done PCR. I've built PCR instruments. I've written papers on PCR. I have patents on PCR instruments. I don't know what you want to know.

Q. Are PCR instruments automated fluid handling systems?

Not the ones -- not -- not typically.

16 So you wouldn't consider an 17 instrument that does PCR -- you wouldn't say that 18 that could be a fluid handling system?

I mean, it could be. You could do PCR in a fluid handling system. Most PCR instruments are -- they don't usually have flow paths or anything like that. They just are a kind of a dispense and

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Bruce Gale, Ph.D.

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A. I don't.

Q. Have you had discussions with anyone affiliated with Cytiva or any of its predecessors on anything relevant to the subject matter of this litigation?

A. Actually, let me just -- I have talked to folks that used to be at Biacore, and I can't remember if Biacore is now part of Cytiva. I'm assuming that it is. And I mean we talked to people at Biacore before, but anyway -- but that's -- I mean, that's totally unrelated to this technology. And I haven't talked to anyone at Cytiva in the last, whatever, that I'm aware of.

Q. Okay. So, I want to turn to your work on this matter. So we talked about the -- the declarations that were offered in 2014 and 2015. In terms of 2016, do you have a sense – I know at some point there were some experiments with the 2040 System. But was there any work that you did in 2016 as it relates to the present dispute? Other than what we're going to get to is that experiments with the 2040 System.

conversation probably next week, so take that however you will.

Q. How good is your recall, sitting here today, about specific events that occurred in 2016?

I remember -- I mean, I remember -- I

think I had a deposition in 2016 related to the IPR.

I remember working on the 2040 instrument with Kevin and Travis. I remember having some conversations, but that's, you know, the -- if you just said, you know, tell me what's -- you know, everything you did, I wouldn't be able to do that. But I also wouldn't be able to do that with what happened last month.

So, I'm not sure how that's (inaudible).

Q. How good is your recall with specific conversations that you had in 2016 relating to your work endeavors?

MR. DAMON: Objection to form.

A. They're -- I'm not going to remember

much of any specific conversation.

Q. Are you somebody who takes notes of your conversations with individuals for work purposes?

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A. Well --

MR. DAMON: Form.

A. My recollection is not great since that was a long time ago, but I believe the IPR may have been going on in 2016 still.

Q. You say your recollection isn't great. What do you mean? Your recollection is not great of the specific work you were doing in 2016?

A. I don't recall if -- yeah. Basically
I don't recall where we were in this case at that -at that point. I don't recall if it was -- the IPR
was done or if it was in the middle of it, or if it
was -- the case stretched on over an amazingly long
period of time, so I don't recall.

Q. Are you somebody who prides yourself on having a good memory?

A. No. I usually remember things — well, I have found that as I've gotten older, that I get so much information that I just don't remember things very well anymore. I remember important things, but things that are not important, they're — they're gone. You know, I will have forgotten this

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A. Not usually.

Q. So in terms of your work, for example, in your lab overseeing your students and having discussions, is that something you keep records of and make notes about?

A. I mean, I -- with regular meetings, I'll, you know, jot down one or two things that maybe we talked about we're going to work on in the next week, but that's about the extent of it. I actually make my students keep notes, and they keep them in places where -- and I bring them to my meetings and I just make sure that those are accurate. And I have access to their notes and that way I can have a conversation with them, and I'm not the one that has to keep all the records.

Q. So let's – let's turn to some exhibits. You issued three reports for purposes of this case within the last few months, correct?

A. That's correct.

Q. Okay. And I'm going to just mark all of them. I know, of course -- I understand you have copies in front of you, so whatever is easier. But

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Bruce Gale, Ph.D.

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1		
2	A. Probably two.	or two things and nothing Mr. Cassingham said down or said, because I don't think he said anything
3	Q. And who were those folks?	or said, occause I don't drink he said anything
	A. I can't remember the woman's name	interesting.
4	that's in my report, Schaffer or something like that.	Q. Bo did you personally and I mean
5	And I talked to John Cassingham.	you - did you personally do any experiments for
6	Q. And what did you talk to Ms. Schaffer	purposes of your analysis in this ease.
7	about?	A. I mean, I worked closely with Kevin
8	A. I think the primary focus of that	Petersen and Travis White to do the experiments. Did
9	questioning is, you know, some questions about how	I push all the buttons? No. Did I push some
10	the N - NGC operates and what kind of preparation	buttons? Yes. I'm I'm not sure what that I
11	you'd have to do to use an NGC system.	what I did or didn't do. But I you know, we did
12	Q. Did you have any discussion with her	it as a group.
13	on any issue beyond what's recited in your report?	Q. So you're saying you're talking
14	A. Probably.	about the experiments that occurred in 2016?
15	Q. On what?	15 A. That's correct.
16	A. I I don't recall. I mean, we had	Q. Okay. And do you have any notes
17	a conversation for half an hour, and the relevant	relating to those experiments?
18	parts I put in my report.	A. Not that I'm aware of.
19	Q. Okay. So you can't recall whether	19 Q. You personally did not take notes
20	there's anything specific that you discussed with her	reflecting the 2016 experiments; that is right?
21	that's not in your report, right?	A. I don't know if I took notes or not.
22	A. Correct.	I don't have any that I relied on or used or anything
1	Q. And what about John Cassingham, what	Page 108
2	did you talk to him about?	² Q. So you're aware that there's the
3	MR. DAMON: Objection, privileged.	³ Exhibit 4 which you referenced in your report, which
4	Excuse me one second.	is a write-up of the experiments, right?
5		5 MR. DAMON: Objection to form.
6	I caution you to not release disclose anything that's privileged, but otherwise	6 A. I don't recall what exhibit number it
7	you can answer the question.	7 is, but I do recall that I submitted a report with my
8	•	is, but I do lecan that I submitted a report with my
9	A. I think John's, I think, the I	WOIR.
10	don't, the chief attorney or whatever for Bio-Rad,	Q. Okay. Who who addicted that
11	and he was present at the discussion with	тероге.
	Ms. Schaffer, I believe. So it was, you know, "Hi,	A. Kevin
12	how doing," "Good to see you again," that sort of	WIK. DAWON. Objection to form.
13	stuff.	13 A. Kevin Petersen and I worked on it
14	Q. Did did Mr. Cassingham add	together.
15	anything or say anything relevant to the subject	Q. And can you if you would look at
16	matter of your report?	it, could you identify which portions each of you
17	A. No. I don't recall. I don't	wrote?
18	remember anything substantive.	¹⁸ A. No.
19	Q. Okay. And you're not sure if you	Q. Did you say you worked on it
20	took notes; is that right?	together? Did you actually draft portions of it?
	A. Yeah, As I said before, I'm I'm	²¹ A. Yes.
21		71. 1 65.
21	not a big note taker. I might have written down one	Q. You personally did?

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Bruce Gale, Ph.D.

Page 109 Page 111 A. Yes. O. Could you see the experiments going 2 Q. But you can't tell me which portions 2 on, as they were occurring? you wrote? 3 Yes, my office window looks directly A. 4 4 MR. DAMON: Objection; form. into my lab. 5 5 This was four years ago. I mean, he Q. Okay. So your testimony was you 6 wrote up a -- he and I talked about an outline. He actually were sitting there watching the experiments? 7 wrote up some pieces, I wrote up some pieces, we put MR. DAMON: Objection to form. 8 8 them together. He -- I don't know. We worked My testimony was that I was present, 9 together on writing the report. and that I could check on them whenever I wanted to. 10 10 Okay. We're going to come back to And you're -- you're basing that off 11 11 this. Did you personally record any videos relating of your recollection from what happened in 2016, 12 12 to the work that was done on the 2040 System? right? 13 13 Not at that time. I mean, I've taken MR. DAMON: Objection to form. 14 14 some videos of -- well, I don't think so. I was Yes. And -- and I'm not saying -- I 15 15 trying to think if I took any other videos of that, mean, those videos are hours long, right? So I may 16 16 but I don't -- I don't think so. or may not have been there the entire time. But I do 17 17 So you personally haven't recorded recall being in the building when Kevin and -- when 18 any videos relating to any work on the 2040 System; 18 Kevin did the experiments. 19 19 is that right? How many times did you -- did you 20 When we -- I know we took some 20 check on the experiment? 21 21 MR. DAMON: Objection; form. pictures. And, you know, more recently when we were 22 22 checking on some things about processors and some You know, I don't -- I don't recall. A. Page 110 Page 112 1 other things like that in the 2040 System, we may I know that I went in, saw it set up. You know, have taken some videos. I don't specifically recall. they -- I mean, I -- he -- Kevin was excited to show 3 3 So you don't know one way or another me that it was working and things like that. So I whether you recorded any videos related to work on went in at least a couple of times. 5 the 2040 System? And do you recall what you б MR. DAMON: Objection to form. specifically said? 7 7 Yeah, I don't specifically recall if A. I don't recall saying -- I don't В a video was taken or not. I mean, the videos that recall now. I've presented to you were not ones that I took Right. So -- so we're talking about 1.0 10 myself. But I've -- I've taken pictures myself four years ago, right? 11 11 personally, and there may have been video or two in A. Yep. 12 12 there. I don't recall. Okay. So is there anything else you 13 13 The videos that were presented with specifically recall, that you can testify under oath, 14 14 your report, you don't appear on those videos, right? occurred in November of 2016, in terms of your --15 15 That's correct. your going in to check or discussions that were had 16 16 O. And who recorded these videos? about the experiments? 17 17 A. Kevin Petersen. I mean, you're asking almost an

28 (Pages 109 to 112)

impossible question, that if it had happened last

in a reasonable way.

week I don't know if I could have -- I could answer

The question, as I interpret it, is,

was I present? Was I involved with this process?

were recorded, correct?

You weren't present when those videos

I was in the building I was in my

office across the hall watching while they did it.

So I don't know what "present" means.

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Bruce Gale, Ph.D.

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- Yes. Did I see what happened? Yes. Do I have
- 2 videos that show that the whole thing worked? Yes.
- 3 Did I understand how they programmed it? Did I
- 4 understand what they moved around? Did I understand
- 5 how the wiring and other things were done? Yes, I
- understand all of these things. I was present, I
- looked at it, I was involved.
 - Okay. But do you recall anything
 - else about specific discussions that occurred during
 - those experiments in November 2016?
 - A. I mean, I meet with -- met with Kevin
- 12 on at least a weekly basis, and often more often --
- 13 or more than that in this time frame. And we'd talk
- 14 about, you know, the experiments, what they were
- 15 trying to do, how they were going about it. I don't
- 16 remember the details, but I remember that they took
- 17
 - So you can't tell me any more about
- 19 specific discussions that occurred in November 2016,
- 20 correct?
- 21 A. No. I mean, well, you have
- 22 everything that I have.

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- 1 took and how hard or easy it was. So I've done that as well.
- O. So when did you do that?
 - A. I did that in 2016. I actually did
- it about a month ago too.
- So when you did it in 2016, which Q.
- modules did you move around?
- You know, I don't specifically
- 9 recall. I believe in the report it says specifically 10 which ones Kevin and Travis moved as part of the
 - demonstration.
 - But you don't recall which ones you Q. moved around; is that right?
- Yeah, I don't. You know, I probably 1.5 started in the top left comer or something like
 - You don't know for sure, do you? Q.
 - A. No.

that.

- Okay. And did you -- did you record Q.
- the time it took somewhere?
 - MR. DAMON: Objection.
 - Did I -- did I record when I did it?

Page 114

- 1 Okay. And you can't tell me more
- 2 about the specific portions of the experiment that
- 3 you personally observed, correct?
 - MR. DAMON: Objection; form.
- 5 Yeah. I don't recall specifically
 - whether I watched this part or that part. But I do
- 7 recall seeing the separations when they were done. I
- recall seeing the, you know, the machine in 9
 - operation. That -- that's what I recall.
 - You mentioned earlier that they moved parts around. Do you remember saying that?
 - A. Yeah. Some of the modules.
 - Okay. So what do you recall
 - specifically about what Mr. Petersen and Mr. White
- 15 did in terms of moving modules around?
 - I asked them to move some modules.
- 17 They -- I think -- I believe they videotaped that.
- 18 They, you know, unscrewed the modules, moved them,
- 19 you know, took one out -- or took two of them out,
- 20 moved the one up. I think they actually moved four
- 21 of them. And I -- actually, I did that on occasion
- 22 with them so I understood how it happened and what it

- Page 116
- Yes. O.
 - A. I don't think so.
- Q. So you didn't do that in 2016? You didn't actually use a stopwatch and record how much time it took you to move modules around, right?
- A. No. Kevin and Travis did that, so I didn't do it separately.
 - And when you said you experimented with moving modules around over the last month, is that right?
 - A. Yes.
 - And when was that exactly?
 - MR. DAMON: Objection.
- I don't know. Five weeks ago, something like that, six weeks ago.
 - Was that before you finalized your first report?
 - I don't specifically recall. I think it was before the second report, but I'm not going to stake my life on that one.
 - Which modules did you move around? O.
 - Moved around specifically -- well A.

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Bruce Gale, Ph.D.

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1 by a panel member," they do not say one way or 2 another whether there can be additional sections, right?

MR. DAMON: Objection; form.

As -- as I said before, the -- what A. it says is that there's a section, you know, a non fluidic section, a fluidic section, and there's no other description of any other sections. And for that matter, there's no suggestion that there's other sections. But it also, as you point out, doesn't say there aren't other sections.

Q. Right. So you -- I just want to understand what you did in your analysis.

You felt like it was appropriate, though, to go to the specification, go to the file history, look at what the inventor said, and use all of that to interpret the claims as part of your analysis; is that what you're saying?

MR. DAMON: Objection.

- I did that.
- O. Did you complete your answer?
- Sorry. I said, yes, I -- I did that.

Page 171

- O. Okay. So this is neither your construction of a panel member from the IPR proceedings, it's neither a construction that Bio-Rad proposed, nor a construction reported document?
 - Sorry, is that a question, or...
- Q. Yeah. Are you aware of whether Bio-Rad proposed the construction that we see in Paragraph 19 of your IPR declaration to the court in this case?
 - A. You know, I don't -- I don't know. I don't recall.
 - O. And -- but we don't see that the court has entered an order adopting that construction of panel member, right?
 - A. Correct.
 - The term "panel member" is agnostic to whether or not there are LEDs as part of the panel member, right?

MR. DAMON: Objection; form.

Yeah, I haven't seen anything that specifically describes LEDs in or with the anyways, there's nothing in the patent that addresses

Page 170

Okay. And you did that for purposes of considering the scope of the claims for your noninfringement opinions, correct?

MR. DAMON: Objection; form.

- Well, I mean, for all of my opinions. A.
- O.

MS. SKLENAR: Let's look at your IPR declaration, which I believe is NN, and let's go to Page 9.

THE TECH: (Complying.)

- There, you see your prosed -proposed construction of "a panel member."
 - Do you see that?
 - A. I see that.
- And you see the -- when we go back and look at the constructions that the court entered from your opening report, that's not a term that the court construed, right?
- A. I --

MR. DAMON: Objection; form.

Yeah, I -- I don't recall seeing

anything on how they construed that.

Page 172

that.

Q. Right. So when we look at the claims that use the term "panel member," it's simply indifferent to whether or not there are electronics or electrical components as part of the panel member, right?

MR. DAMON: Objection; form.

- A. I'm not sure that that's true. I mean, I think, it never contemplated electronics being in the panel member. I mean, the panel member is envisioned as a, as I read it, as, you know, like a solid piece of material that blocks fluids from passing through it.
- The claims don't say that the panel member has to be a solid piece of material, do they?

MR. DAMON: Objection; form.

The claims just mention a panel member. And then again, you go into the specification, you go into the file history, you know, those sorts of documents to try and understand what is meant by the term "panel member."

So once again, for purposes of your

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1 infringement analysis, you're using the specification 2

and file history to try to construe the term "panel

member"; is that fair?

A. Yeah, and my just general

understanding of what the words, you know, "panel"

and "member" mean, you know.

Q. But you'll agree with me that nothing in the claim itself speaks to the composition of the panel member?

MR. DAMON: Objection to form.

 I don't know that that's true. I don't recall -- sometimes they -- some of the claims say a panel member that does something, right. And in that case, then, the claims do construe what the panel member does.

But you're not aware of any claims that say a panel member, for example, is a solid piece of material, right?

MR. DAMON: Objection; form.

No, but it -- yeah, sometimes it describes what it does and then you can interpret, you know, how -- how it accomplishes that or how you Page 175

declarations about the '718 patent, and again, that 2 was from your three declarations from 2014 and 2015,

3 you never, there, in any of those declarations, take

issue with whether any claim terms in the '718 patent were indefinite?

MR. DAMON: Objection; form.

A. Yeah, I -- I don't specifically recall, but I -- yeah, that -- that maybe true.

Okay. So when is the first time that you considered that some of the terms within the Cytiva-asserted patents were indefinite?

Well, as I - as I noted, I don't recall from those previous ones. There may be some discussion of it, but in the more recent reports that I wrote, indefiniteness, you know, popped up when suddenly based on -- I don't know if it's suddenly -but on the way that these are construed and, in particular, how Dr. Wereley construed these sections and claims, it became impossible for me to -- to actually understand what the terms mean.

His use of the -- the terms and the, I guess, the definitions that I understood he was

Page 174

would accomplish that.

Q. And nowhere do any of the claims with the term "panel member" say that the panel member excludes electronics or electrical components, right?

MR. DAMON: Objection; form.

A. I don't recall anything that

specifies that, but it's noted. The -- it's pretty

clear in the patent that there's no contemplation of

9 either fluidics or electronics being in the panel

1.0 member. In fact, it specifically states that they'd

be on opposite sides of a panel member.

So this is another example where you're using the patent specification and file

14 history to construe the claims?

MR. DAMON: Objection to form.

Yeah. Yes, I mean, that's -- I mean,

I don't know how else to construe claims if I don't

18 1.9

Okay. You offered some opinions on the issue of indefiniteness, right?

A.

Q. Now, I noticed that in your prior Page 176

using were impossible to understand, which brings up the concept of indefinite.

So I want to break that down a little O. bit more.

For the terms "fluidics" and "non fluidics," just as they appear in the claims themselves, you don't think that's indefinite, right, just the claims on their faces?

MR. DAMON: Objection to form.

Well, I -- I mean, when I read them, they mean something, right. I can -- I can understand what they mean. As I interpret what Dr. Wereley is saying, then they become indefinite.

Okay. We're going to get to Dr. Wereley. But just the claims -- I want to -- I want to go step by step.

Just the claims with the panel member separating fluidics and non fluidics, you don't think the claims themselves, standing on their own, are indefinite, right?

MR. DAMON: Objection to form.

A. I mean, the -- yeah, as I -- let me

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Page 185 Page 187 1 didn't rule in that way? Yeah. I mean I have -- I mean, I 2 2 give a description here. I know what liquid MR. DAMON: Objection; form. 3 3 chromatography is. It's -- liquid chromatography is My understanding is that there's --4 4 not some, you know -- you know, strange term. It's you know, there -- there could be other -- again, I 5 5 used in the -- in the patents as a general well-known don't know what the -- the judge was specifically 6 б term of art. It's not some, you know, thing that's thinking, but there's some suggestion that there's 7 7 hard to figure out. some other section that could, you know, have -- I 8 8 MS. SKLENAR: With -- with all due don't know, we'll call it electronics or fluidics, or 9 9 respect, I move to strike as nonresponsive. whatever the case maybe, that there's -- but as 10 10 My question was you didn't look to you -- but that does not change the -- the fact that 11 11 see what evidence the judge had already considered there's only going to be - I mean, that the -- the 12 12 that was submitted by Bio-Rad and rejected in the -patent claims and the specification and the - as I 13 13 in the course of preparing your report, correct? said, the -- the file history clearly point out that 14 That's correct. what was invented was strict separation of the 15 15 MR. DAMON: Objection. electronics from the fluidics. 16 16 So let's go to Page 168, So this is another example in 17 17 Paragraph 416, and I want to direct your attention to Paragraph 416 where you're using a specification and 18 18 the beginning part of Paragraph 16. And you're -file history to try and interpret the claims? 19 19 you're talking about the 2040 System, and you're MR. DAMON: Objection; form. 20 20 referencing the fact that they are modules that do As I've stated before, I -- I don't 21 21 not have any electronics on the same site as the -know how else you interpret claims other than to --22 22 of the mounting plate as the fluid handling. Do you to look read and the claim. And if you need any Page 186 Page 188 1 1 other information, you look at the specification. see that? 2 A. I do. You look at the file history. 3 3 And that's something you felt like MR. DAMON: Objection; form. 4 Do you think that there's some sort you needed to do for purposes of your opinion? 5 5 A. of requirement for any of the Cytiva-asserted claims Yes. б 6 that there be no electronics on the same side of the MS. SKLENAR: So why don't I suggest 7 7 panel member as the fluidic section? we go off the record and just -- well, let's go off. 8 8 A. So – so my understanding is that THE VIDEOGRAPHER: Time is 9 9 the -- the patent, that the language, the -- the 11:55 a.m., and we're going off the record. 10 10 specification, the file history all, you know, (Recess taken.) 11 11 required -- or suggested the way that the claims are THE VIDEOGRAPHER: Stand by, please. 12 12 used and the terms in the claims that there's a The time is 12:31 p.m. Mountain Time. 13 13 strict separation between electronics and fluidics. We're going back on the record. 14 14 BY MS. SKLENAR: Q. But -- go ahead. 15 15 A. Yeah. Welcome back, Dr. Gale. 16 16 That's it? Sorry, did you complete O. Did you speak to Bio-Rad's counsel 17 17 your answer? during the break or any of the breaks today about the 18 18 Yeah, so -- yeah, so my understanding substance of your testimony? 19 19 is that there -- that the Way the claims are written I have not talked to them at all. 20 20 would require, you know, a strict separation of Thank you. 21 21 electronics and fluidics. Let's go back to the 2040 System, and

47 (Pages 185 to 188)

let me first ask you about the manual. You're aware

But you understand that the judge

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Q. So continuing down the page, there is a -- there are two chrom test2s. There is a chrom test2 and a chrom test2 copy.

Do you see that?

- A. I do.
- Q. Are those exactly the same?

MR. DAMON: Objection; form.

A. I -- I don't know. I -- I've only looked at the chrom test2.

Q. You haven't looked at the chrom test2 copy?

I have not.

Q. Chrom test2 says -- again, says, as the status, that it's stopped.

Do you see that?

- A. I do.
 - Q. Do you know why that is?

A. I'm -- my general understanding is that it run -- it was running and it stopped, so it needs to be reset or the system needs -- or the -- one of the instrument, or one of the modules may need to be reset or put back in its starting point.

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it in and, you know, we had to figure that part out.

We had to read through the manual to understand how the instrument worked. We had to -- you know, we played with it, tried some things, made sure things worked, you know, made sure we had tubing and other components to run the instrument.

We had to come up with a choice for a chromatography application to demonstrate. We had to acquire the column and reagents for that. And then we, you know, programmed it and set it up.

Q. I want to focus on the programming.

Was there planning that had to be done to -- for the specific program that was entered?

A. I -- I mean, yes, we had to, you know, figure out what the gradient was going to look like. We had to figure out what the capabilities of the various pumps and burettes and valves and things like that were. So we had to, you know, plan what the -- what this experiment would look like and then plan how to implement it.

And some of that was, you know, was done on the fly, let's see what happens if you turn

Page 206

Q. But you don't know specifically why it says stopped; is that right?

A. No, I don't even specifically know when this -- I mean, this -- I think this picture was taken by your team, and I don't know what they did or didn't do with it before they took this picture,

Q. You think the folks that I worked with may have stopped chrom test2?

A. I'm just saying I don't know. If I took this picture I could probably tell you what happened before it, but I didn't.

Q. So let's -- let's talk about chrom test2. What -- what work had to be done prior to the stage that chrom test2 was programmed into the system?

A. Well, the -- I mean, we received the instrument in a crate. It was -- I mean, this was a used instrument, right, so it didn't come with all the nice packaging and all that sort of things. So we had to uncrate it, we had to find a place to mount it in my lab, we had to figure out if we could plug

Page 208

this on; and then others were, once we understood that, we could kind of put together a framework for -- or a flowchart, if you will, or, anyway, some sort of process to allow it to work.

Q. So there was at some point a flowchart or -- or a documented process in terms of planning to program chrom test2, right?

A. You know, I don't specifically recall. I mean, I never made a flow chart, or I don't think that I've ever seen one.

But anyways, there was a process that we had to figure out on how to do it, could have been done -- in which we, Kevin and I and Travis, would chat and they'd, you know, explain what they programmed and what they setup and -- and where we were going, so...

Q. I'm not sure you answered my question.

Was there something documented, whether it be in a lab notebook or anywhere else, that related to the plan for the chrom test2 program?

A. I -- I mean, I don't recall right off

52 (Pages 205 to 208)

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Highly (Confidential
Page 209	Page 21
what's in Kevin's notebook or, you know, the other	¹ MR. DAMON: Objection to form.
documents that whatnot. I think there might have	A. Yeah, I read and I got through a few
been a spreadsheet that had some of the steps in it.	pages last week, but I didn't really get very far.
But you you have what I have on that, so that's	4 Q. And you read that in preparation for
that's the documentation.	5 your deposition, correct?
O. But that's not all the documentation,	6 A. I did.
right? There's some documents that no longer that	Q. And that's something you didn't
you that are no longer in existence, as far as we	mention when I ask asked you a question earlie
know?	about what you reviewed, correct?
A. The only thing that we don't have is	10 A. Oh, yeah, I apologize. I totally
Travis White's notebook, so	forgot about that one.
Q. Yeah. And to be clear, that is	Q. Is Kevin Petersen an honest person?
documentation that Cytiva has asked for that we've	
<u> </u>	A. The stone of the most nonest people
now learned is lost, correct?	you'll evel meet.
A. Well, I	Q. And is he somebody that you find to
MR. DAMON: Objection; form.	be competent?
A. I've never seen it, I never relied on	A. You're asking if he's confident?
it, never used it. So I	Q. Competent.
Q. You've never seen it?	A. Oh, competent. Sorry. He's very
A. Or at least I mean, I yeah, I	skillful, yes.
don't have it. It was never in my possession.	Q. At the time he was doing this work
Q. Have you ever reviewed it?	with you, what was his technical expertise?
Page 210	Page 21
A. I don't believe so.	¹ A. He was working I mean, he was
Q. So what okay. Well, I'm just	using our he's helping us to develop some of ou
going to go for it. How long was that notebook?	³ field-flow fractionation instruments.
A. I said I don't know. I haven't	Q. And what was his I mean, he had
reviewed it.	obtained his undergraduate degree at that time,
Q. And what did the notebook contain in	6 correct?
terms of subject matter?	7 A. Correct.
MR. DAMON: Objection; form.	⁸ Q. Was he a Ph.D. student at the time in
A. There's you know, I don't know	9 2 2016?
whatever notes that Travis felt he might need to	10 A. Yes.
have. I mean, Kevin was the primary primarily	Q. And how many years of post or of
responsible for this, and he's the one that kept most	graduate work had he completed at that time?
of the documentation.	
	A. Tou know, I don't locali light off.
Q. Have you do you understand that	it's probably around three years, something like
Kevin Petersen's been deposed in this case?	15 that.
A. I do.	Q. Is he somebody that you thought was
Q. Have you read his deposition	technically gifted?
transcript?	A. He's a normal student. He he's
 I've I've seen a piece of it or 	good. He did did a good job.

53 (Pages 209 to 212)

Where is he working now?

And what is he doing there?

Mayo Clinic.

something like that. I have not read all of it.

preparation for your deposition today?

Is that something that you read in

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Page	213
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- He's a postdoctoral researcher doing research on medical devices and microfluidics.
 - Q. Is he somebody that you respect?
 - A. Yes.
- Q. Is he somebody that you have thought to have a faulty memory?
 - MR. DAMON: Objection; form.
- Not particularly. He's very good at taking notes much better than I am.
- 10 So do you understand that 11 Dr. Petersen was asked about the role of Travis White 12 in terms of the notebook?
 - MR. DAMON: Objection; form.
 - He may very well been. As I mentioned, I only got through the first few pages. I didn't really get very far.
- 17 And so you didn't read the portion of 18 Dr. Petersen's testimony where he explained what 19 was -- what was contained within the notebook kept by
- 20 Travis White?
- 21 That's correct. Α.
 - Who would have a better understanding

the machine. All the details are there.

2 Well, you understand that we did 3 dispute that, correct?

MR. DAMON: Objection; form.

- 5 A. I understand what? I'm sorry, I 6 missed that.
 - Q. You understand that Dr. Wereley disputes that, correct?
 - I can't even imagine why he would dispute that. That's where the details are.
 - Certainly the machine doesn't identify all the work that went into coming up with the program, preparing to enter the program, and then the time it took to enter the program and the complexity of the task, correct?

MR. DAMON: Objection; form.

- It doesn't show all of those details. It shows the program. And I've used this program. It's really easy to program.
- Well, we're going to get to that. So for chrom test2, what -- what is -- was your specific role with respect to

Page 214

- between you and Dr. Petersen about what was in the notebook that Travis White kept?
 - A. Dr. Petersen.
 - Q. And you would expect that he actually reviewed that notebook; is that right?

MR. DAMON: Objection; form.

- Most likely. I mean, I don't know A. one way or the other.
 - Q. Was he supervising Travis White?
- Yeah. So Travis was essentially a student that asked if he could work in my lab, and so I assigned him to work with Kevin and so he was Kevin's helper.
 - So if -- if Dr. Petersen testified that the lab notebook that Travis White kept had the details for the programming that went into the 2040 System, would you have any reason to dispute that?
- MR. DAMON: Objection; form.
- 20 Not specifically, other -- I mean, 21 the details of the programming are literally on the 22 machine. I mean, I reviewed the program. It's on

chrom test2? A.

- So, in general, I -- I talked to 3 Kevin and said, "Look, we need to, you know, put this 4 instrument out, get it set up, figure out a way to --
- figure out, see if we can demonstrate a 6
 - chromatography application on this instrument."

And -- and I met with Kevin on at least a weekly basis, and maybe more often, to see how he was progressing. And then if he had questions, he'd come into my office, and we'd talk about them.

- Were you physically present when any of the programs that we see in this exhibit -- I believe it's 335. 335. Were you physically present when any of the programs on the 2040 System were input into the system?
- I don't specifically recall. I -you know, I met with Travis and Kevin, and they showed me how it was working and how the power operated. But I couldn't say, hey, it was this program or that one, but I -- they -- I was shown how the program worked.

54 (Pages 213 to 216)

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Q. So you -- you cannot say that you were physically present when chrom test2 was programmed into the 2040 System, correct?

MR. DAMON: Objection; form.

A. I can't say one way or the other.

Q. And you can't say what reference
Dr. Petersen and Mr. White made of the -- the details
of Mr. White's notebook and how they used them in the
programming of the 2040 System, correct?

MR. DAMON: Objection; form.

A. I mean, I don't know specifically how they used it, but as -- as mentioned, the programming is actually fairly easy, and the -- the easiest way to program it and to do it would be just right on the system. It -- it essentially lays out a plan and a time course directly. It's like its own built-in flowchart. It's really nice.

Q. But you had to devise the actual -someone had to devise the actual steps that would occur in chrom test2. Right?

MR. DAMON: Objection; form.

A. Yes, someone programmed it and

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Q. Okay. And for each step, there were different inputs that had to be made per -- per step, correct?

MR. DAMON: Objection; form.

A. Yeah. So, for example, you chose one of the -- one of the modules. You say, okay, burette, we want to, you know, push or pull and do it at, you know, a rate. That -- I mean, it's pretty simple. Burette -- burette, you know, on, push, rate. And then, you set a -- and then there's a -- basically a time course, and then you tell it when to turn it off. Pretty easy.

Q. So in -- in programming a step, the variables would be the module that would do something, the length of time, correct?

A. Correct.

Q. And what else?

A. Depending on the module, it may be able to do multiple things. So I think the -- like the burettes have, like, five things that they can do. The valves, maybe it's got two or three. I know there's just a couple of options, and then you tell

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figured it out.

Q. All right. So someone had to devise exactly what they wanted chrom test2 to do, correct?

A. Right. And you can do that on the instrument. That's why I'm saying the details are on the instrument.

Q. But it's not -- so just so we're clear, how many steps actually are there in chrom test2?

A. You know, I -- I have never counted them.

Q. Do you have a ballpark estimate?

A. They're -- I mean, it depends on how you count steps and other things. Some things had to be repeated. I'm guessing 100 or, I don't know, 200. You know, it's not -- it's not ten, and it's not a million. So --

Q. Your estimate is there are 100 to 200 steps to chrom test2, correct?

A. Like I said, I have not counted them.
That's my vague estimate of just looking over the program.

Page 220

it how long to do it.

Q. And so the steps had to be programmed in a particular order, too, correct?

A. Right. And like I said, it's
 basically on a -- it's on a time sequence. So you -it's -- the time part is visual.

Q. Do you -- did you read Dr. Wereley's opinions about the programming that occurred on the 2040 System?

A. I don't know if I read all of them.
 I read some of them.

Q. He basically said that — and I — I will get the portion so we can look at it together, but just give me one second.

So if we look at Paragraph 345 of this rebuttal report, Page 414, you see that he says by his estimate there were at least 100 steps in the experiments? Do you see that?

A. I do.

Q. Do you -- are you in a position to dispute that?

A. No. I mean, that's essentially what

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Bruce Gale, Ph.D.

Page 233 Page 235 split up the programming duties correct? Actually, I have. Α. 2 O. And when did you do that? A That's true. 3 But you don't know which of the three 3 O. A. I did it about a month ago. 4 4 it was, correct? Q. What program did you input? 5 A. Yeah. It was irrelevant to me on how A. I mean, I -- I went through and I б that specifically happened. edited some of these programs to just see what it 7 And did you -- do you know the amount takes to edit it, and it's actually quite easy. 8 8 When you say you edited them, you of time that it took to input chrom test2? 9 9 I know -- I don't specifically mean you changed them? 10 10 A. recall. I mean, I have some boundaries on that, Yes. 11 11 because I - I know Kevin and Travis only put in a O. And did you do that before the 12 12 lawyers for Cytiva inspected the system? certain amount of time on that, but I don't know 13 13 I -- no. That was probably after. specifically how much it took to program it. 14 14 O. Do you know for certain whether it So it could have been five hours, ten 15 1.5 was before or after? hours, do you have any idea? 16 16 MR. DAMON: Objection to form. I did it in response to Dr. Wereley's 17 comments that this took a really long time. And it's 17 I mean, it could have been a couple 18 18 of hours. It could have been -- I'm assuming it was like, I don't remember it being a long time. I'm 19 going to go look at it and see how long it takes. 19 probably at least an hour. I mean, there's enough 20 20 steps in there it would take sometime to input it. And it was like, yeah, he's just making stuff up. 21 21 But you never entered a full program Some of this was almost surely trial and error. So, 22 22 into the system; is that true? you know, what happens, you know, we do this? Oh, Page 234 Page 236 1 1 that timing was a little bit off, let's adjust it. I've never put a full program in, no. 2 So I'm sure there's multiple iterations to it. Q. So your testimony is just you've 3 3 Do you know for any of the programs edited an exiting program, correct? that reside on the 2040 System --MR. DAMON: Objection to form. 5 5 MS. SKLENAR: And we can go back to Yes. My testimony is that I've -the prior exhibit with the screen shot of the б the main -- I've never done a full program. I've 7 monitor. played with it to see how difficult it was to do, and В THE TECH: (Complying.) it was easy to change times. It's easy to change 9 MS. SKLENAR: Yes. what's going on. It's easy to turn things on and 10 Q. For any of those programs that you off. It's actually quite trivial. 11 11 think may have been done in your lab, do you know for You don't describe any of that in 12 any of them how long it took to input them into the your reply expert report, efforts you took to edit 13 13 2040 System? programs, correct? 14 14 A. No. I don't specifically know, other MR. DAMON: Objection to form. 1.5 15 than, you know, there is a cap on how much time it I don't believe so. 16 16 would have taken, because the whole project was -- I And can you tell me right now which 17 17 mean, I have the exact hours of how much time Kevin of the programs you edited? 18 18 spent on the project. I specifically went in to look at 19 19 Q. Have you personally -- personally, chrom test2 to see how long it was, how -- what

59 (Pages 233 to 236)

So is chrom test2 that resides on the

modules were specifically involved in the program.

Yeah, so that's the one that I looked at.

yourself, correct?

and I mean you -- have not programmed the 2040 System

by inputting any sort of steps into the system

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Page 265

MR. DAMON: Objection; form.

A. If you want to do a custom liquid
 chromatography application, that's what everybody has
 to do.

Q. Well, I -- let's not talk about custom. Let's just talk about a routine liquid chromatography application.

MR. DAMON: Objection; form.

Q. Is it your opinion that somebody who wanted to do just a routine liquid chromatography application would have to go through all of the steps that Mr. — Dr. Petersen and Mr. White went through for the 2040 System to do any sort of liquid chromatography?

MR. DAMON: Same objection.

A. They would essentially have to go through, yes, the — the same steps. They would have to plan out what they are trying to do, what their chromatography experiment is. They'd have to plan out the — you know, the time and the operations that they're going to use. They'd have to plan out what columns they want to use. They have to plan out

Page 267

A. I mean, all that I've looked at -sorry. All that I've looked at is the NGC doc--you know, operating documents, and it's clear that
it's not, you know, pull it out of the box and push
the button, and it -- and it does chromatography.
So --

Q. Can you cite me to the document you're referring to?

MR. DAMON: Can you let the witness finish, please?

A. The – only to go back through, I know when I did my original reports back in 2015 that, you know, I looked at those documents, and it's clear that it's not, you know, just walk up, push a button, and -- you know, get it out of the box, push a button, and walk away.

Q. But you haven't looked to see how Bio-Rad markets its systems to customers and how -- how it touts that its systems are easy to use in terms of setup in running liquid chromatography, correct?

MR. DAMON: Objection; form.

Page 266

the -- you know, any data processing or any other things that they want to do.

There's no liquid chromatography system that I'm aware of that you take it out of the box, and it runs itself.

Q. And so for the purposes of the your opinion on that in terms of the efforts that are required to get a commercial liquid chromatography system to run, you're relying on your discussions with -- her name is Ms. Schaffer, is that correct, at

Bio-Rad?

A. That's correct.

Q. And you don't cite any documents from

Bio-Rad for purposes of that portion of your opinion, correct?

MR. DAMON: Objection; form.

A. If they're not there, then I don't

cite them.

Q. Okay. So you haven't gone to look at any internal Bio-Rad documents that talk about the length of time in terms of setup required to run liquid chromatography on the NGC system, right?

Page 268

A. So I talked to Ms.

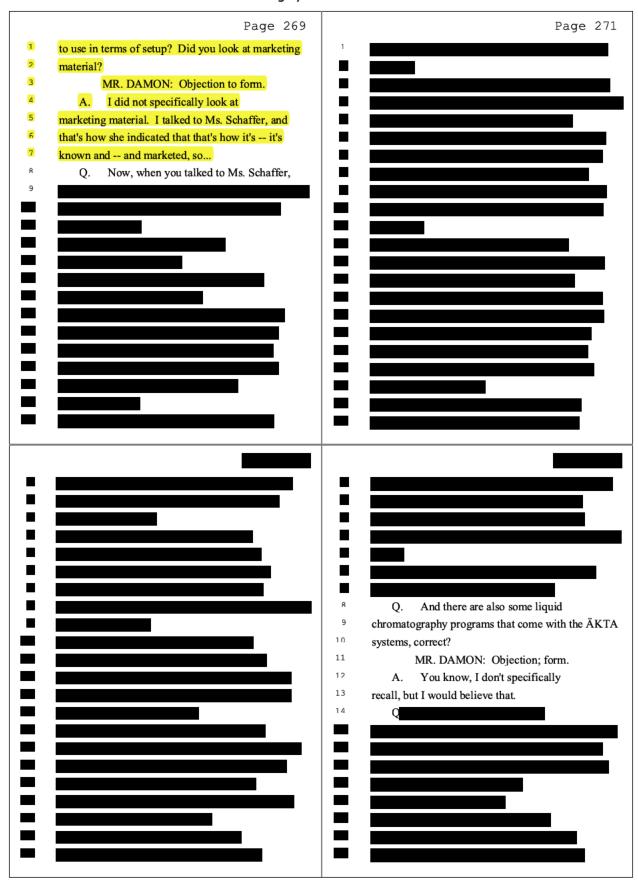
So the -- I mean, you look at what we did with the 2040 System, we had no technical support. We had no help. We had no -- we bar--- barely had any documentation, and we were able to do it in a very reasonable amount of time.

MS. SKLENAR: I move to strike as nonresponsive.

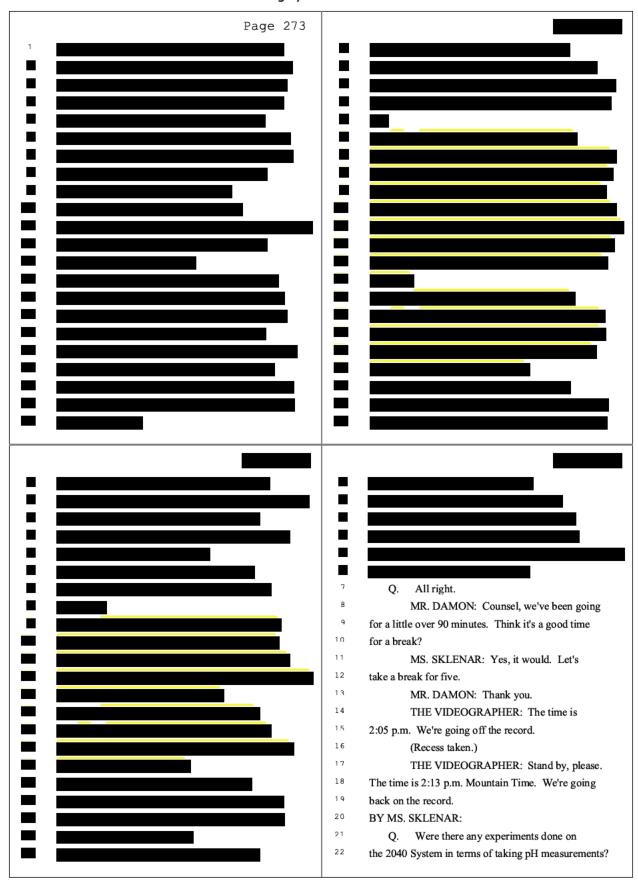
Q. Dr. Gale, my question was did you look to see how Bio-Rad looks to market its system to customers and how it touts that its systems are easy

67 (Pages 265 to 268)

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Page 297

understand.

I'd say they're similar.

Q. And did you express to anyone at

Bio-Rad that that was your view?

A. I've never been asked that question.

Q. So you've never discussed – like,
 for example, with Ms. Schaffer, you've never talked
 to her about the 2040 System and explained to her
 what was involved in programming the 2040 System,

10 correct?

MR. DAMON: Objection; form.

A. I don't specifically recall if we explained at all how the 2040 System worked. We were mostly asking how does the NGC system work. The user interface on the NGC system is probably more modern. It can be done on a computer. You can actually program the Applikon instrument on a computer as well, and I suspect that that would even make it even easier than what — what we did.

Q. Dr. Gale, I have limited time left.
 So I'm going to ask you to try to stick with me and answer my questions.

Page 299

A. I did walk through with her what we did to -- to use the 2040 System and asked if that's typical for an NGC system, and she said you basically have to do the same thing with an NGC system.

Q. So I just want to be clear. You said a minute ago that maybe 20 seconds' worth of time -- you talked about the 2040 System -- and now are you telling me you spent more than 20 or 30 seconds talking about the 2040 System with Ms. Schaffer?

A. Yeah, now that -- once you asked me that other question, I remembered that we did have a conversation where we explained for probably two minutes the general approach that we'd taken with the 2040 System. And then she basically responded that that was similar to the steps that you'd need to take for the NGC system.

Q. And – and so you're suddenly remembering a lengthier conversation with Ms. Schaffer; is that right?

MR. DAMON: Objection; form.

A. Yeah, I mean, I don't remember all the details of the conversation, but I do remember

Page 298

You've never talked to Ms. Schaffer

about the 2040 System and explained to her what was

involved in programming the 2040 System, correct?

MR. DAMON: Objection; form.

A. I don't recall. We -- we may have at

a very high level, I mean like 20 seconds' worth or

⁷ 30 seconds' worth of time saying this is how the

2040 System is used. And then talked about maybe how

that compares. But it was -- I was most interested

in how the NGC system worked.

Q. And you never showed her the test report that's Exhibit 4, correct, that describes the November 2016 experiments?

MR. DAMON: Objection; form.

A. I have never shown it to her. She may have seen it some other way, but I never showed it to her.

Q. And you never showed her the system interface for the 2040 System and walked her through the steps of what had to be done to program the 2040 System, correct?

MR. DAMON: Objection; form.

Page 300

that we explained to her here is the general approach, here is how we use the Applikon instrument,

and, you know, what's different between how you do

4 that and what you do with an NGC system.

Q. So Ms. Schaffer, if I – if we took

her deposition would say, "I absolutely walked

through and compared for the 2040 System and the NGC

system the steps and length of time that it would

take to operate each to do liquid chromatography.

That's exactly the conversation we had"?

MR. DAMON: Objection; form.

A. We did not specifically say, you know, here's how much time it took to do X, Y, or Z. We talked about here's the — the steps that you have to take to set up the Applikon instrument. How is that different from the steps you have to take to set up the NGC system. And I'm sure she would agree that

Q. Okay. Well, we'll see.
So have you ever done -- I asked you about Karl Fischer titration. Have you ever done endpoint titration?

we had that conversation.

75 (Pages 297 to 300)

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Page 349 Page 351 You discuss a number of license focused on two. 2 agreements in your rebuttal report, correct? 2 Q. Did someone provide you with a copy 3 of those licenses? I do. 4 4 O. Okay. And you say you --A. I believe so. 5 MS. SKLENAR: Let's turn to Who? Q. Paragraph 314. A. Bio-Rad, the counsel. 7 Did you discuss either of those with THE TECH: (Complying.) Q. 8 Dr. Kearl? And you refer to four factors that 9 you evaluated, right? A. I did. 10 10 A. Yes. Q. Do you note your discussion in here? 11 11 I mean, the discussion with O. And where did you get those factors? A. 12 12 I believe those factors were, I mean, Dr. Kearl, he -- he asked me some questions about 13 13 these licenses. things that were readily apparent to me that you'd 14 14 want to compare. I was trying to remember if there Q. But you don't note that in here; is 15 15 that right? was some legal thing that the -- Bio-Rad's counsel 16 16 pointed out to me that should be considered, but A. No, I --17 17 those were things that I considered that would be MR. DAMON: Objection; form. 18 18 important, I guess. I don't recall what if I -- sorry 19 19 So you don't know where those factors I'm -- I don't do this all the time. I'm not sure if 20 20 came from, if they came from Bio-Rad's counsel or if I'm supposed to note that or not, so I may have 21 21 you came up with them, right? missed that. 22 Well, that's not what I said. These Did you review any other license Page 350 Page 352 1 are -- these are things that I thought of or that -agreements produced by Bio-Rad and Cytiva other than 2 2 some of these were things -- clearly some of them the you've summarized? 3 were things that I thought of and I'm not sure if Actually, I think there were like six 4 they were some additional ones that said, oh, you or eight or some number of license agreements. I 5 should also include this. So I - I don't recall. don't remember specifically. They were -- there were 6 more than two. You then reference that you reviewed 7 You don't summarize any agreements evidence regarding all of the license agreements that Q. 8 you understand Dr. Kearl is relying on, that's in Paragraph 317? s, correct? 10 10 A. That's correct. A. Yes. 11 11 Okay. So you reviewed evidence 12 regarding all of the license agreements that 13 Dr. Kearl is relying on, that's what you say, right? 14 I mean, I looked at -- I don't know 15 exactly all the documents that Dr. Kearl is relying 16 on, but I had documents that were produced for me 17 that, I guess, I was asked to review. So that was my 18 understanding, is that these were what Dr. Kearl was 19 using. 20 You then summarize information 21 relating to licenses, right? 22 I believe that's correct, that I

88 (Pages 349 to 352)

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Page 389 1 CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC 2 I, Amanda Gorrono, the officer before whom the foregoing depositions were taken, do hereby 3 certify that the foregoing transcript is a true and correct record of the testimony given; that said 4 testimony was taken by me stenographically and thereafter reduced to typewriting under my direction; 5 and that I am neither counsel for, related to, nor employed by any of the parties to this case and have 6 no interest, financial or otherwise, in its outcome. 7 IN WITNESS WHEREOF, I have hereunto set my hand this 25th day of November, 2020. 8 9 1.0 11 12 13 14 NDA GORRONO, CLR 15 CLR NO: 052005 - 01 16 17 18 Notary Public in and for the State of New York 19 County of Suffolk 20 My Commission No. 01G06041701 21 Expires: 01/07/2023 22

EXHIBIT 2 FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC,

Plaintiffs

C.A. No. 18-1899-CFC

Consolidated

v.

DEMAND FOR JURY TRIAL

BIO-RAD LABORATORIES, INC.,

HIGHLY CONFIDENTIAL

Defendant.

 $({\bf TECHNICAL}) - {\bf ATTORNEYS'} \ {\bf EYES}$

ONLY

REBUTTAL EXPERT REPORT OF DR. BRUCE GALE

handling unit"	removed from positions in the housing and that has a
	standardized size and shape that allows it to be
	exchanged with another fluid handling unit"
Claim Preambles ("An automated	The preambles are claim limitations.
liquid chromatography system	
comprising" / "A method of	
modifying a fluid flow path in an	
automated liquid chromatography	
system comprising" / "A method for	
building an automated liquid	
chromatography system, the method	
comprising"/ "A liquid	
chromatography system arranged to	
provide a controlled fluid flow	
through a chromatography column,	
the system comprising")	
"liquid chromatography system"	Plain and ordinary meaning
"automated liquid chromatography	Plain and ordinary meaning
system"	
"wherein the system is capable of	Plain and ordinary meaning
performing automated liquid	
chromatography"	
"non-fluidics section" / "non-fluidics	"a section of the interchangeable fluid handling unit that
section" / "non fluidics section"	includes electrical components and does not include
	fluidics components"
"a fluid handling section" / "a fluidics	"a section of the interchangeable fluid handling unit that
section"	includes fluidics components and does not include non-
	fluidics components"

- 23. In all cases, I applied the agreed claim constructions or the Court's constructions as one of ordinary skill in the art would interpret them in light of the specification and the file history in performing my analyses and rendering my opinions in this report.
- 24. In this regard, it is my opinion that Dr. Wereley has misconstrued the Court's claim construction at least with respect to the terms fluidics section and non-fluidics section in Paragraphs 57-58 of his report. He has done so, apparently, because he did not state in his opening report that he reviewed the file history where the inventors of the asserted patents made certain statements explaining what their inventions were not. By failing to review those statements, Dr. Wereley interprets the Court's claim construction (and statements made during

- 42. Moreover, when one of ordinary skill in the art performs an analysis of the patent, the statements the inventors made to obtain their patents, and the actual modules that have been accused, they would only be able to come to the conclusion that there is no external fluidics section in the two pump and one injection valve module that Dr. Wereley has relied on to prove infringement of this element.
- 43. Throughout the specification of the asserted patents, the inventors stress that there needs to be separation of fluidics and electronics components to ensure that electronics are not harmed when changing fluid connections and when a leak occurs. See, e.g., Col. 2: 28-32 (a liquid handling panel to separate fluidics and electronics); Col 6: 17-620(in one embodiment, the panel member essentially separates the fluidics section from the electronics and internal electronics); Col. 6: 10-29 (noting various arrangements, including with and without a panel member such that the electronics are separated from the fluidics through the use of such components as a suitable sealing arrangement between the housing opening and the external fluidics side of the module); Col. 7:7-25 (noting air tight sealing between the component positions and the non fluidics section and noting configurations, such as that claimed, where fluids are strictly on one side of the fluid handling panel and the electronics are strictly on the other: "According to one embodiment, fluids are strictly restricted to the fluidics section 30 of the interchangeable modular components 26, but in alternative embodiments, only fluid connections are restricted to the fluidics section 30 allowing fluid to "cross" the fluid handling panel inside the non-fluidics section 30 of the interchangeable modular component 26.")
- 44. I note that nowhere in the patent is there a description of anything other than two sections in a module, a fluidics section and a non-fluidics section. To the extent there is some other intermediate section, it is nowhere described in the patents or how to determine it.

Nonetheless, even if one of skill in the art were to assume that such a section could exist, they would recognize that such a section would need to satisfy the goals of the invention, which is to keep the fluids separate from the electronics. Dr. Wereley never considered this requirement, which is present not only in the passages cited above, but also by the named inventor Mr. Lundkvist, Cytiva's previous expert, Dr. Scandella, and statements that the inventors made during prosecution to obtain the patents.

45. For example, the named inventor Mr. Lundkvist testified: "If it can get liquid on the electrical component, it will not be our concept. . . So –in our concept it, has to be separated with a sealing, those two parts – the liquid and the electrical stuff." Ex. 2, 10/17/14 Dep at 141:14-19.

```
14
                       And it was important to separate the
      15
             fluidic section from the electrical components,
             such as circuit boards, because the front side
      16
      17
             where they have the flow path, the -- customer
             handled it with the finger -- finger tights --
      18
             when you screw it in, the valve, for example?
      19
      20
                       When you have the customer not have
             mounted it in the proper way, they can maybe get
      21
      22
             loose and spraying all around with the liquid?
      23
                       And it's important to protect that
      24
             leakage so it won't go in the electrical circuit
      25
             board, so -- the electrical component.
46.
```

47. Ex. 2, 10/17/2014 Lundkvis Dep. At 140:6-25.

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11
                         So it would not be your concept if you
       12
               had electrical components on the front within
       13
               the flow path?
                         If it can get liquid on the electrical
       14
               component, it will not be our concept.
       15
                         Okay.
       16
       17
                         So -- in our concept it, has to be
       18
               separated with a sealing, those two parts -- the
               liquid and the electrical stuff.
       19
48.
```

49. Ex. 2, 10/17/2014 Lundkvis Dep at 141:11-19.

```
20
                         So you can't -- based on what you said
        21
               before, you don't want -- also based on what
               your patent says -- you say that the electrical
        22
        23
               components -- the circuit boards, the motors,
        24
               the pH sensor, the UV sensor --
        25
                   A.
                         Yeah.
        1
                                     LUNDKVIS
         2
                         -- all need to be inside the housing
                   Q.
         3
               in that non-fluidic section, right?
         4
                         I'm referring to the concept again.
         5
                         It's just important to separate those
         6
               with a sealing?
        7
                         And if it's outside or inside, it
         8
               doesn't matter for the concept.
         9
                         Yes, if it's sealed off, that's very
       10
               important, so it won't -- they won't
       11
               interfere -- the liquid won't interfere -- let
        12
               it come down to the electric circuit board.
50.
```

- 51. Ex. 2, 10/17/2014 Lundkvis Dep at 144:20 145:12.
- 52. In fact, Mr. Lundkvist testified that the separation was so important and central to his invention that he did not consider a system in which the fluidics and electronics were not

separated as something that he had invented. Ex. 23, 06/26/2020 Lundkvis Dep at 151:24-155:15

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6
                        Is fair to say that if a system
       7
           does not require the fluidic components to
       8
           be separated from the electrical components,
           is it fair to say that such a system is not
       9
      10
           what you consider to be your idea or your
      11
           invention?
      12
                        MR. NISHIMOTO:
                                        Objection, form.
                        Yes, my idea was to have a -- a
      13
                  Α.
           wall to separate these, the fluidics, from
      14
            the electronics, yes.
      15
53.
```

- 54. Ex. 23, 06/26/2020 Lundkvis Dep at 151:24-155:15 (only 155:6-15 reproduced here).
- 55. Plaintiffs' first expert similarly identified the importance of the separation of electronics and fluidics to the invention at pages 54-56 of his deposition reproduced below:

	Q What's the purpose of this invention, as 10:39:56
	you understand it, that's described in the '718
	patent?
18	A Well, as I see it, this invention allows
	the user to have greater flexibility in terms of how
	he uses his his fluidics handling system, and in 10:40:12
	terms of the different types of applications that
	can be used, and in terms of easily reconfiguring
	the system to accommodate new uses and possibly new
	environments where the machine is used.
	Q What's the reason for separating the 10:40:34
	Page 54
1	fluidics sections from the electrical components?
2	A Well, one reason is to protect the
	electrical components. The electrical components
	typically are sensitive and easily damaged by
	contact with with fluids, particularly the kinds 10:40:53
6	of fluids that are used in the fluidics section.
7	Q Any other reason?
8	A Probably other reasons. One one reason
9	is to make it easier to contain it, to control the
10	environment of the electronics components. 10:41:10
11	Q Anything else?
12	A There if you let me think for a minute,
13	I could come up with some more.
14	Q Go ahead.
15	A But those are 10:41:24
16	Q Go ahead and think.
17	A Well, another is that in a laboratory
18	environment, one is solutions are constantly
19	getting splashed around when they don't when you
	don't intend them to be. A piece of tubing breaks 10:41:35
21	or pops off of a fitting, or a beaker tips over and
22	you end up with with salt solution splashed on
23	the front of your instrument. These are the kinds
	of things that happen in the lab, and that an
25	instrument instrument such as these automated 10:41:52
	Page 55

56.

1 liquid handling systems, you'd like them to be able
2 to cope with that.

EX.

- Over and over again during the prosecution of the applications that lead to the 58. patents and in order to distinguish their invention over the prior art, the inventors relied on and pointed to the same need for separation of fluidics and electronics in their invention to ensure that the electronics would not become wet and therefore likely damaged. For example, when addressing and distinguishing the Mourtada reference from their invention, the inventors stated: "The reason for separating the fluidic and non-fluidic sections is to stop the non fluidic sections" getting wet when pipes etc. are reconfigured on the machine, and/or when the modular components are rearranged. None of those features are disclosed in or obvious from Mourtada ... The apparatus as proposed in claim 1 thus provides the unexpected advantage that not only can component positions be reconfigured easily and thereby simplify the fluidic interconnection of the components used, but alternatively, fluidic reconfiguration can be carried out without precious electrical pars becoming wet or contaminated. This is particularly advantageous where toxic or corrosive, or pathogenic liquids are being handled. On the one hand the organisation of the components can be optimised, and they can be protected in use. These advantages are not present in Mourtada or any prior art cited." Ex. G at GEHC 001477- 1478. (emphasis added)
- 59. With respect to the Bergstrom prior art the inventors were distinguishing they stated: "Applicants submit that Bergstrom has given no thought to what happens when one unplugs a module and gets the electrical contacts 19 wet which will be inevitable since the contacts 19 appear to be housed in the cup shaped aperture 14, or what happens to the processor 55 in Figure 10 when that gets wet. *Id.* at GEHC 001451.

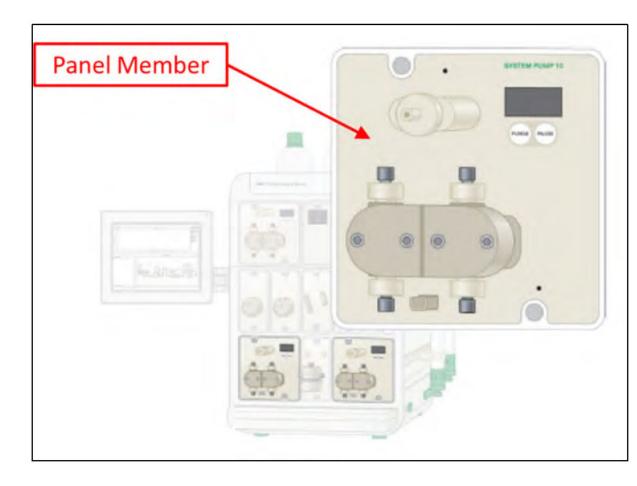
- 60. The inventors said the separation requirement was even more important in liquid chromatography systems as opposed to other automated fluid handling systems: "The features of claim 17 as applied to liquid chromatography are particularly advantageous because such a system is typically used for many different initial experiments to prove the principles for larger scale operations. In such use, the system components are frequently reconfigured and in so doing the advantages of fluid and non-fluid separation, as claimed in claim 17 become even more significant, for example by providing a housing for liquid chromatography components including a liquid handling panel for accepting the components and avoiding contamination of electrical components." Ex. G at GEHC 001418.
- 61. To ensure that the goals of the invention were met, the inventors described in great detail during the prosecution when they were distinguishing the prior art what was necessary to separate the fluidics from the non-fluidics sections and what would not be considered separation something that still had a likelihood of the electronic components of a module becoming wet when fluid connections were changed, modules were rearranged, or a leak occurred. If that was possible, then one of skill in the art would recognize that the fluidics and the non fluidics (electronics) were not in distinct sections that were separated. Rather they would be in the same section.
- 62. And as will be explained in more detail in the following paragraphs that is what is present in the Bio-Rad accused modules. One of ordinary skill in the art reading the file history would only be able to come to the conclusion that the external electronics that Dr. Wereley recognizes are present in the accused Bio-Rad modules (the two pumps and injection valve, Wereley ¶ 116) are not in sections that are distinct from the fluidics sections. Rather, they are in the same section and not separated in the manner the inventors said they needed to be to be part

of the invention and distinct from the prior art. For example, the accused pump module has switches, a display, and LED lights which the user sees, as well as a PCB and ribbon electrical connector in the overlay. *See e.g.*, Wereley ¶ 142, showing pictures of accused pumps in Ex. 48, 49 and ¶ 150 quoting from manual Ex. 47 stating that there are switches on the exterior of the pump modules. *See also* Ex. 25.

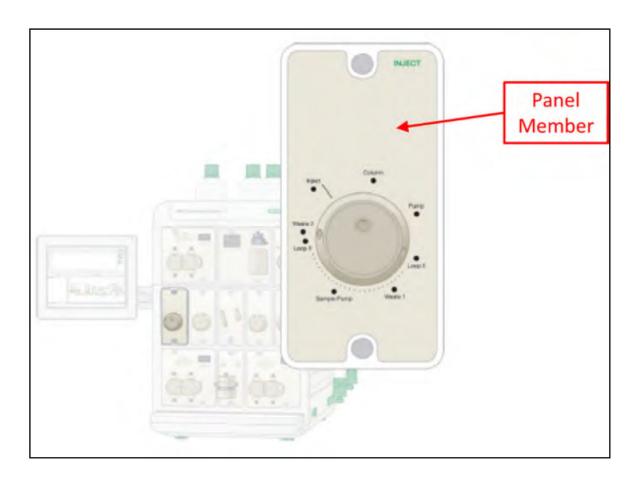
- 63. In particular, the inventors pointed out that for there to be separation of the electrical components and the fluidic components of a module such that they were in separate sections and unlikely to have fouling/wetting or contamination of the electrical components if there was a leak of the fluidic components, there had to be a particular spatial relationship between the components.
- 64. In particular, the inventors said multiple times that the fluidics and the electronic components of a module need to be on opposite sides of a panel for a) them to be separated, b)to ensure that the electronics would not get wet if there was a leak, and c) to define the electronics and the fluidics as being in separate sections. In discussing Bergstrom, the inventors said: "The modules of Bergstrom do not separate their fluidic and electrical parts (where they have electrical parts). Further, those paths cross into the base plate at about the same region. The detector module 10 of Figure 10 illustrates that fluid and electrical parts are adjacent, not on either side of a panel. Ex. G at GEHC 001451.
- 65. After stating that Bergstrom gives no thought to making sure that electrical parts do not get wet, which I cited to above, the inventors then reemphasize, one paragraph later, the separation point and again state that the fluidic and electronic parts need to be on opposite sides of a panel in the invention. In fact they not only state that the electronic parts in a modules need to be on opposite sides of one panel, but on opposite sides of two different panels: "These

problems in the Bergstrom design are not addressed in Burger, but are cleverly addressed in presently claimed invention by separating the fluidic and non fluidic parts of fluid handling units across a fluid handling panel and across a panel member of the modular components, which inhibits the problems mentioned immediately above." *Id*.

- 66. The accused modules do not meet those requirements for multiple reasons and therefore do not have external fluidics sections, ones that do not have electrical components, for multiple reasons.
- 67. First, having failed to refer to any of the File History statements which require the fluidics components of a module to be separated from the electrical components by at least two different panels to be considered by one of ordinary skill in the art to have distinct fluidics and electronics sections, Dr. Wereley provides no detailed analysis of the alleged panel member of the modules that are supposed to separate fluidics from electronics components of a module to meet the requirement that the electronics and fluidics are in separate sections.
- 68. Dr. Wereley purports to analyze the panel member as claim element 1(h) at paragraphs 138-147. But the analysis is cursory and conclusory again. At paragraphs 139 and 141, Dr. Wereley pastes pictures of a Bio-Rad system pump and a sample inject valve and simply draws a red arrow and red box and concludes these are the panel members of the modules. I reproduce those figures below:



69.



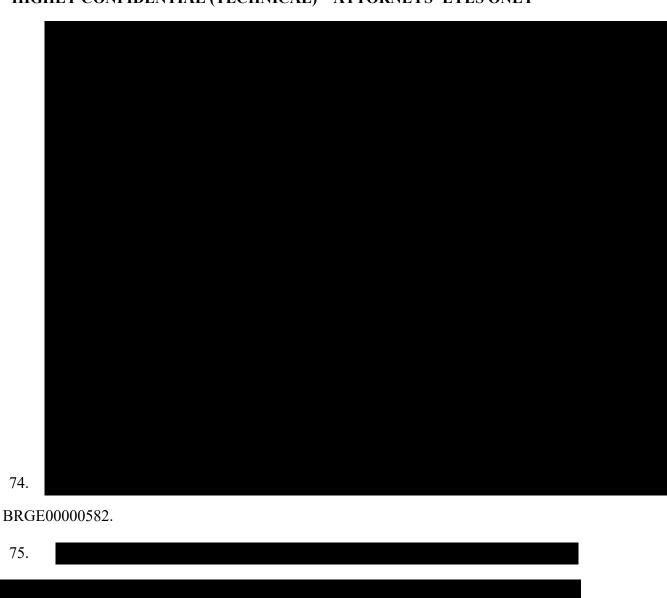
70.

71. At paragraph 145, Dr. Wereley cites to testimony from two Bio-Rad witnesses to establish that what he has pointed to is a panel member. But, the testimony does not do so. Both Mr. Bland, and Mr. Chapman, whose testimony is quoted, state that the component that Dr. Wereley points to as the panel member is actually two separate parts: there is 1) "a front plate" and an "overlay" *Id.* at ¶ 145. Mr. Chapman testified that

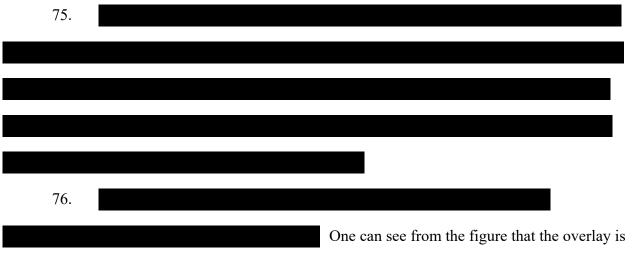
Id. at p. 91

(quoting Chapman testimony).

- 72. In other words, Mr. Chapman's testimony makes clear that the faceplate is what is responsible for allowing the module to be mounted on the instrument housing. I have confirmed this by holding and physically examining a number of the Bio-Rad modules. The specification of the asserted patents describes the panel member as the structure that is used to attach the module to a component position in the in the liquid handling panel. *See e.g.*, '420 patent Col. 6:30-34 ("As is disclosed in FIGS. 4a to 4d, the interchangeable modular components 26 comprises a panel member arranged to separate the fluidics section from the non fluidics section and for attachment to a component position in the liquid handling panel.")
- 73. The first problem with Dr. Wereley's analysis is that he equates two distinct parts, the face plate and the overlay and calls them collectively the panel member. *See* Wereley at ¶ 146, referring to the "face plate/overly structure" The assembly drawing from one exemplary module,



Ex. 6, BRGE00000582.



full of electronics. There is a printed circuit board which appears brown or copper colored. There is a ribbon wire connector, and there are LED lights shown on this module. Other modules also have a display that the user can see as well as switches for the user to activate. The

LED lights, the display and the switches are not trivial elements added to avoid infringement as I understand plaintiff's counsel portrays them. Rather the LED lights tell a user where to make fluidic connections and the display enables users to easily see values and parameters on the modules.

Even Plaintiffs' witnesses Mr. Soderman testified that the LEDs are useful Ex. 26, 115-116 ("Q: What do you think about those small LED lamps? A. Good to have for a beginner.") and Bio-Ra employees have pointed out that it is a feature which users like and appreciate. Ex. 27, Chapman Depo Tr. at 206:21-207:13.

- 77. In any event, given that the overlay and faceplate are two separate structures held together by a few drops of glue, one of ordinary skill in the art would not consider them collectively the panel member.
- 78. But, even if one of ordinary skill in the art reading the specification considered the overlay and faceplate to be the panel member, they would not consider the electronics that are part of the overlay to be in a separate section of the module from the fluidics section as Dr. Wereley concludes with no analysis. At paragraph 149 of his report, Dr. Wereley merely says: "I see no reason why the fact that certain of the modules have LEDs or displays integrated into their panel members takes them outside the scope of the claim language. For one, as discussed, the fact that these are non-fluidics components is not relevant since under the Court's claim construction, only the fluidics section cannot have non-fluidics components such as electronics, and the panel member is a different section in that it is neither a 'fluidics section' nor a 'non-fluidics section'."

- 79. Dr. Wereley makes the statement that he does not see any reason why the electronics "integrated into the panel members takes them outside the scope of the claim language without analyzing the file history to see how the inventors characterized their invention and how they treated what is a fluidics section. When the file history is examined, one of ordinary skill in the art can only come to the conclusion that what Dr. Wereley points to as a panel member and a fluidics section of the accused modules do not satisfy the requirements of the claims and are not consistent with how the inventors characterized their invention or the fluidics section in the file history. As a result, Dr. Wereley's opening report fails to meet Plaintiffs' burden of establishing the existence of this element in the accused modules.
- 80. Dr. Wereley merely concludes with absolutely no analysis that anything "integrated into the panel member" is a different section from the fluidics and electronics sections. I do not agree and neither would one of ordinary skill in the art who read the specification and the file history.
- 81. First, the inventors addressed this very issue in the file history. With respect to fluidics and electronics and the existence of separate sections, the inventors stated that the fluidics and the electronics need to be on either side of a panel. See Ex. G GEHC 001451 (The detector module 10 of Figure 10 illustrates that the fluid and electrical parts are adjacent, not on either side of a panel") (emphasis added); ("Bergstrom has given no thought to what happens when one unplugs a module and gets the electrical contacts 19 wet which will be inevitable since the contacts 19 appear to be housed in the cup shaped aperture 14... These problems in the Bergstrom design are not addressed in Burger, but are cleverly addressed in presently claimed invention by separating the fluidic and non-fluidic parts of fluid handling units across a

fluid handling panel and across a panel member of the modular components, which inhibits the problems mentioned immediately above.")(emphasis added)

- 82. The first quote from the inventors in the above paragraph shows that they consider the panel member, which like all physical objects has a thickness, has two sides, (*i.e.* "either sided"). It is apparent Dr. Wereley did not consider this fact. If he did, Dr. Wereley could not make the accused panel member consistent with the inventor statements by claiming that rather than two sides, the panel member has four sides: 1) the side the user sees, 2) the inner side of that side in the thickness of the panel, 3) the side that is mounted against the housing, 4) the inner side of that side which is also in the thickness of the panel. In standard English usage, which does not differ from the way one of ordinary skill in the art would understand what the inventors said, "either" indicates two options.
- 83. The same conclusion would be reached by one of skill in the art reading the second quote from Ex. G at page GEHC 1451 that I quoted above that the inventors made regarding the arrangement of the fluidics and electronics of a module. In the second quote, again distinguishing Bergstrom, the inventors stated that the fluidics must sit "across" two different panels: 1) the fluid handling panel and 2) the panel member. The accused products satisfy neither of these requirements and would not be considered by one of ordinary skill in the art to therefore contain a fluidics section with no electronics in the section.
- 84. As with the word "either" in the first quote, one of ordinary skill in the art would understand the use of the word "across" with reference to the fluidics and electronics of a panel being across two different panels to refer to the panel having two sides and the electronics and fluidics of a module lying on the opposite sides. That is not the case with the accused modules

- 85. According to Dr. Wereley, the electronics are "embedded" in the panel member and thus part of a separate section from the fluidics. In addition to the fact that this embedded notion is inconsistent with the two statements I quoted above stating that the fluidics and electronics should be on either side of the panel member and across two different panels, the liquid handling panel, which the electronics and fluidics in the accused modules surely are not, and the panel member which they also are not it is also inconsistent with other statements and the physical arrangements of the components in the Bergstrom reference that the inventors distinguished.
- 86. In the file history, the inventors stated that one can see how Bergstrom arranged his components in Figs. 1 and 4(a) where you can see a flow line 5 in baseplate 1. Ex. G at GEHC 1449. I reproduce those figures and others from Bergstrom (Ex. 21) below.

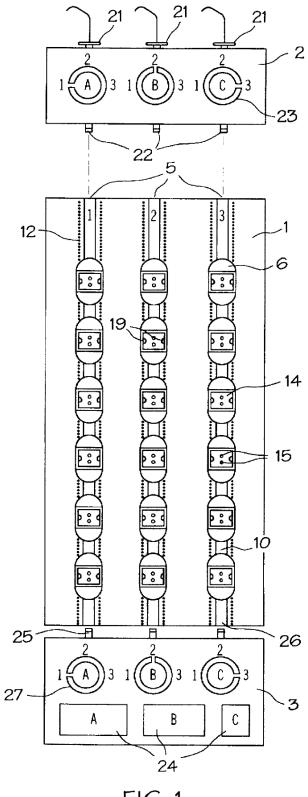
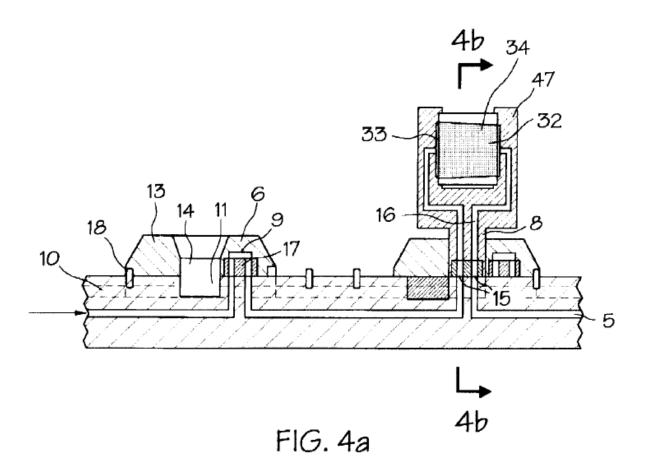
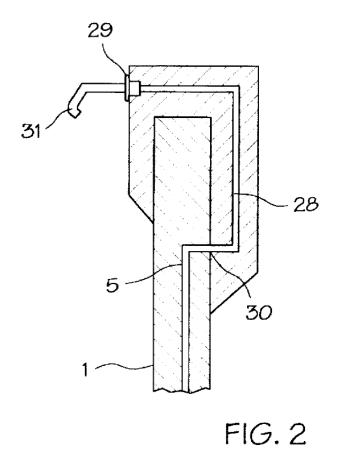


FIG. 1

- 88. The inventors repeatedly described the flow line "5" as being adjacent to the electrical connectors "12" and therefore, having fluidics which are not separated from the electronics in the base plate "1" which had been equated to the panel member. Ex. G, GEHC at 1449-1451.
- 89. Dr. Wereley's claim that electronics integrated in the thickness of the panel member are in a separate section and separated from the fluidics section of the module is inconsistent with what the inventors said about Bergstrom. As can be seen in Figure 4(a), which I reproduce below and which the inventors referenced when distinguishing Bergstrom as not having separate fluidics and electronics sections that were separated, the electronics lines "12" in Bergstrom are integrated in the base plate/panel member and are distanced from the fluid lines "5" which are also embedded in the base plate.
- 90. In Fig. 4(a) one sees a blow up of a single module "10" in base plate "1". One can see in the figure that the flow line "5" is within the thickness of the base plate
 - 91. This is also shown in Fig. 2 which I also reproduce below.

92. as





93.

94. Similarly, the Bergstrom specification states that the electrical lines "12" which are depicted in Fig. 1, are also embedded in baseplate 1. *See* Ex. 21 Bergstrom 5,766,460 at Col. 3:50-54 (One or more lines/conductors (12) for signal and power transmissions from or to connected modules may be arranged in the base plate (1) preferably along the flow lines (5).". Nonetheless, even though the electronics were integrated in the thickness of the baseplate/panel member and so too were the fluid lines (5). Although those lines were parallel or near each other, they would have to be embedded in different thickness of the baseplate/panel member. But, consistent with the prior statements of the inventors that the fluids and electronics in a module had to be on different sides of two different panels, the inventors did not consider Bergstrom to have modules with separate fluid and electronics sections or have those sections separated.

- 95. Consequently, Dr. Wereley's analysis that having electronics integrated in the thickness of the panel member creates a different section that is separated from the fluidics section, is not consistent with the file history and one of ordinary skill would not come to the same conclusion that Dr. Wereley did. Rather, after reading the portions of the file history I have discussed thus far, one of ordinary skill in the art would conclude that the accused modules do not have an external fluidics section—one that has no electrical components.
- 96. Dr. Wereley's analysis that integrated electronics are a separate section from the fluidics does not consider at all that such an analysis fails to account for the accused devices and the analysis regarding them being inconsistent with the purpose of the invention. As I detailed previously, the patent, the inventor and plaintiff's prior experts also stressed that the purpose of the invention was to have electronics and fluidics in distinct sections that are separated and sealed from each other so as to keep the fluids from wetting or damaging the electronics such as when fluid connections are being changed or if there is a leak. That is not the case in the accused devices.
- 97. As I explained above and as can been seen in the photo of the assembly procedure for the inject valve that I reproduced in this report, the overlay attaches to the face plate only with a few drops of glue. That method of attachment is not sufficient to seal the electronics which Dr. Wereley says are "integrated" in the "panel member" from fluids on the module. To confirm this, I physically examined at least two different modules recently, a pump module and a pH module with respect to the relationship between the overlay and the faceplate. I confirmed by looking at these physical samples that fluid that leaks from the modules would not be sealed from the electronics Dr. Wereley describes as being integrated in the panel member.

- 98. To be sure of this, I also spoke to Bio-Rad employee Joe Hilario. I understand that Mr. Hilario has experience with and responsibility for assembly of Bio-Rad modules and is familiar through his experience with whether fluid can seep into and wet the electronics that Dr. Wereley states are integrated in the panel member. Mr. Hilario confirmed, consistent with my examination of the modules, that in fact leaking fluid can wet the electronics that Dr. Wereley describes as being embedded in the panel member. My examination and Mr. Hilario confirmed that there is no sealing member, like a gasket, that seals the overlay to the faceplate and prevents electronics from getting wet. Consistent with this fact, The Bio-Rad products do not carry the same classification specified by a certifying organization as the Cytiva products, with respect to the degree that electronics and fluidics are separated from each other.
- 99. Consequently, the actual facts related to the accused modules demonstrate that they are not consistent with the purpose of the invention, to separate the fluids in a module from the electronics and therefore, have them in separate sections where the likelihood of the electronics getting wet is low. This fact also demonstrates that Dr. Wereley's conclusion that electronics "embedded in the panel member" as Dr. Wereley describes them, are not in a different section from the fluidics. For one of ordinary skill in the art to determine that fluids and electronics are in separate sections, they should be arranged and separated in such a way that the purpose of the invention will be fulfilled—electronics will not get wet if there is a fluid leak.
- 100. Yet another set of representations in the file history from the inventors that are inconsistent with Dr. Wereley's summary conclusion that electronics integrated in the panel

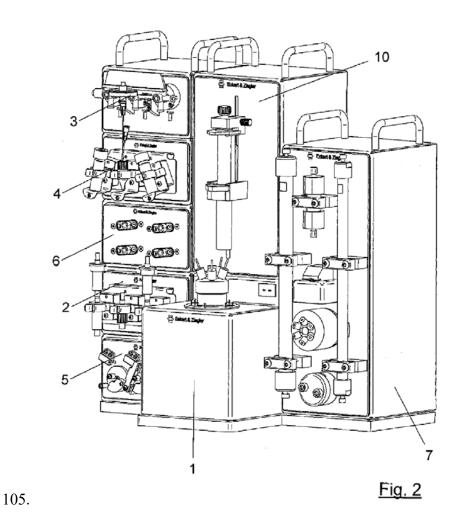
member⁴ of the accused modules are in a separate section from the fluidics are the representations about the Hess reference.

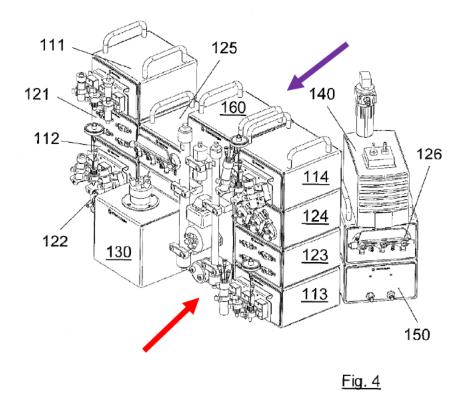
- 101. The applicants distinguished the Hess reference as not having a fluidics section separated from a non fluidics section because the modules in Hess had an electrical connection coming out of the back of a module while there were fluids on the front of the module. *See* Ex. G at 1416-1417 ("Therefore, the boxes of Hess must be electrically interconnected, and it follows that these connections are external to said boxes and not internal to any housing...This means that the bus connections cannot be internal to said boxes or internal to any 'housing.' On the contrary, the bus connections must be external to said boxes to make sense of the description. Therefore, in Hess, respective non fluidics sections are not internal to any housing as claimed.").
- 102. The inventors recognized that Hess had an internal electronics sections that was separated and sealed from the fluidics section: *See* Ex. G at 1423 ("Since the Hess design was conceived with radioactive product processing in mind [e.g. see abstract] the need for sealing each box and electrically connecting each box such that liquid radioactive contamination does not penetrate the boxes or box electrical interconnections is very important, but results in a costly system.").
- 103. Nonetheless, the inventors stated that Hess was inconsistent with the invention because although it had electronics inside a housing that was separated and sealed from fluidics, there was one electrical component, a bus interconnection that was external and not internal to said housing in Hess. *See, e.g.*, Ex. G at 1424 ("Therefore, the boxes of Hess must be

⁴ I am simply repeating Dr. Wereley's description of the arrangement but not agreeing with it.

electrically interconnected, and it follows that these connections are external to said boxes and not internal to any 'housing'."). According to the inventors, the electrical connections had to be at the back of the boxes. *Id.* at 1416 ("So by process of elimination, bus connections [in Hess] have to be at the back of the boxes – there is no other place for them if the boxes are stackable and fit side by side as illustrated.").

104. Below, I have reproduced an exemplary figure from the Hess reference (Ex. 22). In Fig. 2 below one of ordinary skill in the art can see that the system has fluid components on the front of the boxes, while the bus connections that the inventors described are on the opposite side and cannot be seen.





107. In this arrangement, one of ordinary skill in the art would see the bus connections at the back of the boxes, purple arrow, would be on the other side of at least two walls from the fluidics, which are indicated with a red arrow. Even with this two wall separation, the inventors said the arrangement was inconsistent with their invention. There is no way to square this representation about Hess, with Dr. Wereley's claim that electronics integrated in the panel member are in a separate section from the fluidics in the accused modules. The electronics in Hess are on the other side of two walls from the fluidics, not right next to them as in the accused modules, yet the inventors said this was not separation and not its invention because there was a single electrical component that was not inside the housing even though there were many other electrical components inside the housing.

106.

108. The inventors further stressed why this type of arrangement was not its invention.Not only did the inventors consider that their invention had to have the fluidic and electronic

components of a module separated, such that there were distinct and separate fluidics and electronics sections in the module, but the separation had to be accomplished in a particular way which is inconsistent with Dr. Wereley's analysis.

- 109. Even if one of ordinary skill in the art would assume, contrary to the facts, that electronics integrated in the panel member of the accused products somehow separated them from the fluidics in the modules and protected them from getting wet, this is not consistent with the invention as the inventors represented it to the Examiner. The inventors unequivocally stated, over and over again, that any protection of electronics of a module had to consist of "collective" protection in which one module's electronics were being protected in the same way and in the same structure as all the other modules' electronics.
- 110. The inventors described the collective protection of the electronics of a module of the invention as follows in distinguishing it from Hess in Ex. G at 1414-1415:

According to the claimed invention, the liquid handling panel of the housing, together with the panel members of the modular components is arranged to separate the fluidics sections with respect to the non fluidics sections of the modular components such that the respective fluidics sections are external to the housing and the respective non

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111. GEHC 001414

Appl. No. 13/376,929

Amendment dated May 28, 2014

Reply to Office action of March 17, 2014

fluidics sections are internal to the housing. In general terms, as pointed out in the present

application [0060], this concept allows for collective liquid protection of internal parts of

the modular components present inside the housing and separated from the fluidics

sections by the fluid handling panel/members. In contrast, in the design of Hess, each

independent module needs to be sealed and resistant to liquids in order to provide a safe

working environment and to comply with relevant regulations for fluid handling systems.

Since the Hess design was conceived with radioactive product processing in mind

[e.g. see abstract] the need for sealing each box and electrically connecting each box such

that liquid radioactive contamination does not penetrate the boxes or electrical

interconnections is very important, but results in a costly system. The presently claimed

system provides a much lower cost alternative to the Hess design because the collective

protection of the housing claimed negates the need for the individual sealed boxes of

Hess.

Applicant submits also that there is no disclosure in Hess of the separation

concept of the fluidic sections and the non fluidic sections as claimed in present claim 1

"such that said respective fluidics sections are external to the housing and said respective

non fluidics sections are internal to the housing". In Hess, each individual box must be

connected to the bus in some way, but nothing detailed is illustrated concerning any

connection. In this regard, the most pertinent description in Hess appears to be [0077] and

[0078]:

[0077] To further reduce the complexity of the configuration, the system may include an intelligent bus system which recognizes connected components.

Advantageously, standard connecting cables can be employed which only differ by having different lengths.

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112. GEHC_001415

43

- 113. At best, (which I do not agree with) what Dr. Wereley describes as electronics integrated in the panel member to create a section distinct from the fluidics section would be an example of individual protection of fluidics from electronics in each module that the inventors distinguished their invention from over Hess. Such individual protection does not provide the "collective protection" that the inventors said was necessary in their invention. In other words, the electronics integrated in each panel member of each module in the Bio-Rad accused modules and system are not protected from the fluidics by being inside a housing that protects them all. Rather the integrated electronics that Dr. Wereley points to are each protected individually.
- 114. A person of ordinary skill in the art reading the inventors' statements about Hess would recognize that if in Hess, a single electronic cable exiting the back of a module, in which the cable was spaced apart from the fluidics at the front of the module by at least two walls and a much greater distance than the electronics in the Bio-Rad accused devices are distanced from the fluidics, did not constitute a distinct section that was separated from the fluidics section, then neither does what Dr. Wereley calls the electronics integrated in the panel member of the accused modules.
- 115. For these reasons, the accused devices do not have an external fluidics section. Similarly, the subsequent elements that I will discuss in the following paragraphs relating to the non fluidics section and the separation of the fluidics from the non fluidics by a panel member and the non fluidics section being internal to the housing and separated from the fluidics by a liquid handling panel when the module is inserted into the housing are also not met.

2. Element [1.f]: "an internal non-fluidics section"

- 116. Element [1.f] of the '420 patent requires "an internal non-fluidics section."
- 117. The NGC System does not infringe this element because the NGC System does not include "an internal non-fluidics section" as required by claim 1 of the '420 patent. As

detailed with respect to element 1(e) in the prior paragraphs, which I incorporated herein, each of the Bio-Rad accused modules contain either LED lights, a display or both that are visible to the user and on the same side of the panel member as the fluidics. The pump modules also have electronic switches on the same side of the panel member as the fluidics. They also contain electronics such as a PCB and ribbon line in the "overlay" shown in the assembly documents cited and that are exhibits to this report. These are all part of the non-fluidics section and cannot simply be considered a separate section from the electronics that are inside the housing.

- 118. In paragraphs 118- 126 Dr. Wereley concludes that there is a non fluidic section, one that he believes does not have fluidics, by pointing to electronics inside the housing. But, as discussed previously, Dr. Wereley does not at all consider the File History. As I discussed previously regarding element 1(e), when the file history is examined, one of ordinary skill in the art can only come to the conclusion that there is not a non fluidics section in the accused Bio-Rad modules.
- 119. For example, the Hess reference certainly had electronics that were sealed in a box and separated from the fluidics that were outside the housing and on the front face visible to the user. *See* Ex. G at 1423 ("Since the Hess design was conceived with radioactive product processing in mind [e.g. see abstract] the need for sealing each box and electrically connecting each box such that liquid radioactive contamination does not penetrate the boxes or box electrical interconnections is very important, but results in a costly system."); *See* Figs. 2 and 4 reproduced above from the Hess reference showing the fluidics.
- 120. Nonetheless, as shown in the previous element, the inventors stated Hess was distinct from their invention because there was a single electrical component, a connector between modules, that exited from the back of each module. The inventors considered that

single electrical line to be part of the non fluidics section of each module and not separated from the fluidics of each module.

- 121. There is no way to distinguish the arrangement of Hess and the arguments the inventors made regarding there being electrical components not separated from fluidic components in the Hess modules from the arrangement in the Bio-Rad accused modules. Each of the Bio-Rad modules has electronics that are not inside the housing, just like Hess. Therefore the Bio-Rad modules do not have a non fluidics section.
- 122. Further as discussed with element 1(e), it is not proper to call the electronics in the accused devices that are "integrated in the panel member" a section that is distinct from either the electronics inside the housing or the fluidics outside the housing. For example, as discussed previously, with respect to the figures of Bergstrom that I reproduced above showing the flow channel 5 and the electrical lines 12, the Bergstrom reference has electronics and fluidics integrated in a baseplate structure, yet the inventors did not consider them to be distinct sections that were separated. Moreover, the inventors stated that for electronics and fluidics to be in separate sections, they had to be on opposite sides of a at least two different panels—the panel member and the liquid handling panel. Ex. G at 1451. There is no way for this to be true and the Bio-Rad accused modules to meet the claim limitation.
- 123. As I discussed previously, I do not believe the overlay is the panel member. Thus, the electronics that Dr. Wereley states are "integrated in the panel member are actually in the overlay and on the same side of the panel member (faceplate) as the fluidics. Moreover, even if one considers the overlay and the faceplate as being a single unit that is the panel member, the fluidics and electronics are still not on opposite sides of the two required panel members—the liquid handling panel and the panel member as the inventors stated they must be. Ex. G at 1451.

- 124. For all these reasons and those discussed with respect to element 1(e), the three accused Bio-Rad liquid handling units do not have a non fluidics section.
 - 3. Element [1.h]: "a panel member arranged to separate the fluidics section from the non-fluidics section"
- 125. Element [1.h] of the '420 patent requires "a panel member arranged to separate the fluidics section from the non-fluidics section."
- 126. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of the prior two elements for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as integrated in the panel member. "Integrating" as shown with the arrangement of Bergstrom, does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being integrated in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).
 - 4. Element [1.i]: "wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."
- 127. Element [1.i] of the '420 patent requires "wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional

array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."

- 128. I have discussed why this element is not met with respect to my discussion of elements 1(e), 1(f) and 1(h). I incorporate those discussions fully for this element.
- 129. The NGC System does not infringe this element because the alleged housing lacks the underlined portions of the claim element: "a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."
- 130. In summary, the failure of proof for this element is most easily demonstrated with reference to the inventors' discussion of the Hess reference. As discussed with respect to elements 1(e) and 1(f), in the Hess reference, each module had electronics sealed in a box and fluidics visible from a side that one can consider the front of the box. The inventors pointed out that what the examiner was considering the modules also had a single electrical connection exiting the back of the box. See e.g., ¶¶ 107-112 herein. For this reason, they concluded that Hess did not have a non fluidics section internal to said housing and a fluidics section external to said housing. There is no way for one of ordinary skill in the art to distinguish the arrangement in Hess that the inventors said was outside the scope of their invention with the arrangement in the accused modules. In the accused modules, there are electronics outside the housing. Those electronics cannot be a section that is distinct from the electronics that are inside the housing, just like the single electronic connection in Hess was not distinct from the electronics contained in the sealed boxes. Because the electronics inside the sealed boxes in Hess, that the examiner

considered a housing did not constitute a non fluidics section that was internal to said housing when inserted, one of ordinary skill in the art could not also consider the electronics that Dr. Wereley considered to be embedded in the panel member to be a non fluidic section that is distinct from the electronics that are inside the housing in the Bio-Rad accused modules.

- 131. Therefore, Dr. Wereley has failed to meet his burden to establish the existence of this element in the accused fluid handling modules.
 - 5. Element [1.k]: "wherein each interchangeable modular component includes a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"
- 132. Element [1.k] of the '420 patent requires "wherein each interchangeable modular component includes a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."
- 133. The NGC System does not infringe any claims of the '420 patent because the alleged interchangeable modular component lacks "a dedicated cpu unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus" as claimed.
- 134. In particular, Dr. Wereley, at paragraphs 160-170 of his report where he discusses this element, has not established and met his burden of proof that each module acts independently to perform operations after receiving instructions over the bus. First, I do not believe that Dr. Wereley has used the proper definition of the CPU's on the modules acting independently. Second, I do not see proof under the definition that he does use that each of the accused modules acts independently of other modules.
- 135. Dr. Wereley interprets the "independent" language in the claim to mean independent of other modules. *See* Wereley ¶167. But that is not how one of ordinary skill in

the art would interpret that limitation. The specification gives two alternatives for control. First it describes the master control unit communicating with each module over a bus and those control signals issued by the MCU controlling the modules. *See* Col. 7: 57-60 ("As mentioned above, the chromatography system may comprise a master control unit 40 arranged to communicate with all modular components e.g. 1-26 over a system bus 42 such as a CAN-bus or the like"). In that embodiment, something other than a CPU on the module would instruct the module what to do. The control function could be carried out by for example a particular voltage/current that would make a pump operate at a certain rate. (e.g., A high signal makes the motor operate at one rate and a low signal makes it operate at another rate).

- that would allow the module to <u>independently</u> perform operations in response to instructions over the bus. *See* col. 7: 60-63 ("In one embodiment, each modular component is provided with a dedicated CPU unit allowing the component to independently perform operations in response to instructions over the BUS 42.") One of ordinary skill in the art would <u>not</u> read that alternative to do nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (e.g., A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely forward it to another device to create that same current or voltage or simply translate that instruction into a different format.
- 137. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that

signal indicates and what the MCU would have done on its own, something that is independent of the signal the MPU sent.

- which I detailed in my invalidity report. In the 2040, the burette modules have a CPU located directly on them. The 2040 User Manual indicates that the burette modules have very precise control the ability to vary flow in one of 10,000 increments. To maintain such precise control, one of ordinary skill in the art would recognize that the burette module, using its CPU is independently monitoring the flow value and constantly making adjustments to ensure the set value is being maintained. In that situation, the CPU on the burette is operating independently of the master control unit which would have only sent the original instruction for what the initial parameter should be.
- 139. Given that the specification describes the back to back situations where either:

 1)the Master Control Unit controls the operation of the module, and contrasts that with 2) the situation where the CPU independently controls an operation of the module in response to an instruction from the MCU, one of ordinary skill in the art would not understand the independent control to be control that is independent of what is occurring in other modules as Dr. Wereley does.
- 140. Contrary to what Dr. Wereley concludes at paragraph 167, the mention of the MCU and the fact that the MCU needs to send instructions would not lead one of ordinary skill in the art to interpret independently to mean independent of other modules just because the CPU must receive some signal from the MCU.

As I explained in the

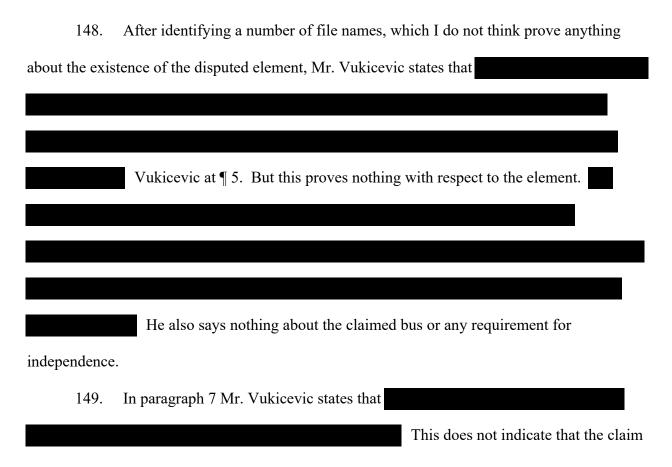
paragraph above relating to what the 2040 burette module does, just because a CPU receives an instruction from an MCU does not mean that functions carried out by the CPU cannot be independent of the MCU command.

- 141. There is no reference in the specification to modules communicating with each other in relation to the control function. Rather the two embodiments in the specification that are directed to this limitation relate to the MCU controlling the module, or the CPU on the module receiving a signal from the MCU and then acting independently of the MCU in carrying out some function on the module.
- 143. Mr. Bland's testimony that Dr. Wereley cites also does not support his construction of this element of the claim. All that Mr. Bland testified was that in the accused system, $Id. \ \text{at} \ \P$ 168, pages 108-109. But, that does not mean that is what the claim term in the patent means.

That would be like saying that a car that can maintain its speed independent of a driver pressing the accelerator pedal, defines the meaning of a claim in a patent written about a different car that says the car operates independently of operator control. Independent of operator control could certainly relate to an autonomous driving system, not simply cruise control. One needs to see how the term is used in the patent, not some application outside the patent. There is no way to link those facts to determine the meaning of the claim element. I understand that the element of a patent claim must be interpreted in light of what is disclosed in the specification, not with reference to an accused device. If the latter was the method of interpretation, than one would always interpret the claim with the way the accused product worked and there would always be infringement of every patent.

145. I understand that Bio-Rad identified its understanding of the independent requirement in its non-infringement contentions. *See e.g.*, ROG Response 6 supplemented on May 22, 2020. By choosing not to address this construction at all in his opening report, I understand that neither Dr. Wereley nor Mr. Vukicevic can raise it either one of their responsive reports.

- 146. Next, even if Dr. Wereley's construction were correct, that independent means: "that the particular module's operations be independent from the operations of other modules installed in the system."
- 147. First, I have reviewed the report of Mr. Vukicevic who allegedly studied the source code to show that it operated in a way consistent with the claims. I do not find that what he states in his report establishes that. For example, nowhere in his report does Mr. Vukicevic state that the Master Control unit issues commands over a bus to a CPU on each of the accused modules that then uses those commands to control the operation of the module independently of other modules. The closest he comes is in paragraph 5, but that paragraph does not say that commands travel over a bus and control each of the accused modules independently of other modules



limitation is being used. It does not identify what is sending the signals, how they are being sent and to what on the CU.

150. So, nothing that I see in Mr. Vukicevic's report establishes that the accused
devices function in the manner claimed. In fact, in the next few sentences, Mr. Vukicevic state
Again, this does not establish that the MCU is sending the commands, over a bus to
the CPU on each module. Nor does it establish that each CPU is acting independently from the
CPU on any other module as Dr. Wereley interprets the limitation.

- 151. Dr. Wereley's independent analysis of this element also does not establish the existence of this element in the accused device. Thus, Dr. Wereley has failed to meet his burden in his opening report.
- 152. In particular, nothing in paragraphs 160-170 of Dr. Wereley's report establishes that the CPU on each of the accused modules is receiving signals over a system bus that then cause it to carry out operations on the module. Moreover, nothing in those paragraphs of Dr. Wereley's report indicate that any signals that the CPUs receive are from the MCU which is the only description the specification contains for where the signals must be coming from. See Col. 7: 54-67, Description of Fig. 8 Dr. Wereley nowhere in his report identifies where the signals are originating from. Thus he has failed to meet his burden to establish this element. Additionally, see next element. Further, the separate computer that a user of the Bio-Rad accused devices uses to input information and which contains the user interface is not the MCU as described in the specification. Rather, it is a distinct control computer. See Col. 8: ("The master control unit 40

comprises a system controller 46 for communicating with internal and external components and control computers (not shown)"). Indeed, having a master control unit outside the housing would also be inconsistent with how the inventors distinguished Hess during prosecution, as it would require a bus outside of the housing.

- 6. Element [1.1]: "wherein the master control unit is arranged to automatically identify interchangeable modular components"
- 153. Element [1.1] of the '420 patent requires "wherein the master control unit is arranged to automatically identify interchangeable modular components."
- 154. The NGC System does not infringe any claims of the '420 patent because the alleged master control unit is not "arranged to automatically identify interchangeable modular components" as claimed. The evidence that Dr. Wereley cites at paragraphs 171-174 shows that this element is not met. Rather than showing that the MCU automatically identifies an interchangeable modular unit, the testimony of Mr. Bland that Dr. Wereley cited shows that See e.g., Wereley at ¶
- 155. The NGC Instrument guide also does not establish that the MCU identifies each interchangeable module that inserted into the machine. All the guide says is: "Each module has a unique electronic ID that enables the system to recognize its function when the module is placed into the bay. For example, the system can distinguish between a sample inject valve module and a sample inlet valve module even though they each occupy a single wide slot." See Wereley at ¶171.

Id.

- 156. But the fact that the system identifies a module does not mean the element is met. The system is composed of multiple elements. The claim element, however, is very specific. The MCU is the component in the system that must identify the module inserted into the housing. The fact that the identity may be passed on to the MCU at some point after it is identified by some other component of the system does not satisfy the element. One of ordinary skill in the art would understand identify to mean the component that makes the identification, not any component that later receives the information. This is consistent with the specification which states it is the MCU which makes the identification and not CPU's on modules. Col. 8: 8-14 ("According to one embodiment, different component modules are automatically identified by the master control u nit, whereby they may be moved essentially freely between different positions. Moreover, the master control unit may be arranged to provide said information to Chromatography control software whereby experimental setup and planning may be performed."). This passage makes clear to one of ordinary skill in the art that having one device in a system identifying a module is different from that device passing that identity on to other devices in the system as occurs in the accused system.
- 157. Last, I see nothing in Mr. Vukicevic's report that shows that Plaintiff has met its burden of establishing the existence of this element. In paragraph 8 of his report, Mr. Vukicevic states that

 Vukicevic, ¶ 8. First, Mr. Vukicevic

is not even sure if this is the case. Second, nothing in this sentence or in any other part of Mr. Vukicevic's report establish that it is the MCU, which identifies the modules as the claim requires.

- 158. Therefore, Dr. Wereley, Mr. Vukicevic and Plaintiffs have failed to establish the existence of this element in the accused devices.
 - 7. Element [1.m]: "wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least three of the pump, the sensor unit and the fluid control valves are interchangeable modular components"
- pump modules are not interchangeable modular components because the interchangeable modular components of claim 1 need to have the fluidics and non fluidics sections of elements 1.e and 1.f as well as the separation requirements of elements 1 (h, i, j) and the independent operations requirements of element 1.k and identification requirement of 1(l) which the sample inject module and the two pump modules do not have as described previously which I incorporate herein. The same is true for the other fluid handling modules that Dr. Wereley identifies as alternatives to the pump and inject valve for this element.
- 160. Further, with respect to the UV module that Dr. Wereley relies on to satisfy this claim element, he identifies a sensor unit, but neither the Bio-Rad single or multi-wavelength UV detectors qualifies as interchangeable modular units that can satisfy this element because neither has the required fluidics and non fluidics sections, a panel member for separating those sections, and a liquid handling panel for separating those sections, nor does either satisfy the requirement that the electronics be internal to the housing when inserted.
- 161. One of ordinary skill in the art reading the file history, specification and claims would conclude that the Bio-Rad single and multi-wavelength detectors are not interchangeable modular units as required by the claims. In fact, the inventors addressed this very type of component and unequivocally stated that such a detector did not come within the claims of its invention.

162. In distinguishing the Bergstrom reference the inventors pointed to the detector module 10 as not being within the realm of its invention. *See* Ex. G at GEHC 1450. In particular, the inventors first said:

lines/conductors 12 [column 3 lines 50-58]. Further, column 7 lines 3 to 11 describes signal communication to a detector module 40 (Figure 10) via contacts 20 on the module and corresponding contacts 19 (Figure 1) on the base plate 1. The detector 40 also includes a processing unit 55, which is very likely to be electronic in nature and conductors 41 which both appear to be next to liquid paths. It is suggested that other modules will have corresponding power and signal paths: "other modules (for instance valve modules) may be provided with power and signal transmission lines/conductors." [column 7 lines 8-10].

163.

164. The Bergstrom specification at Col. 7: 3-11 describes that the detector module can be based on pH, UV, IR, conductivity, capacitance refractive index, etc.:

7

function in the form of valves, filter, matrices, additional connection, detectors, etc.

FIG. 10 illustrates a detector module. The detector unit (40) may be based on pH. UV. IR. conductivity, capacitance, refractive index, etc. The transmission of signals from the 5 module is effected through lines/conductors (41) and contacts (20) to corresponding contacts (19—shown in FIG. 1) in the connecting device. Correspondingly, other modules (for instance valve modules) may be provided with power and signal transmission lines/conductors. Detector modules 10 may be equipped with signal processing units (55).

165.

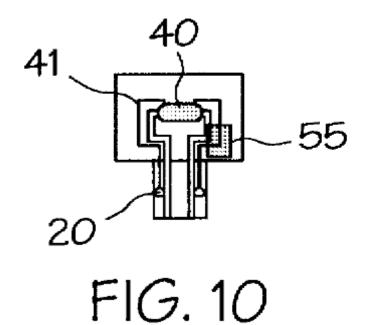
166. The Bio-Rad UV modules have both a UV detector and a conductivity detector on them as can be seen in the images below along with Fig. 10 from the Bergstrom patent:



167.



168.



169.

- 170. Further images of the Bio-Rad UV and conductivity detectors are attached as an exhibit to this report.
- 171. The inventors made it clear and unequivocally stated that a detector, such as a single or multiwavelength detector which Dr. Wereley has accused of satisfying this element cannot.
- 172. The statements were so clear that even Cytiva's prior expert Dr. Scandella recognized that the UV detector had electronics on the same side of the panel member as the fluidics section. That testimony is reproduced below:
 - 11 BY MR. BILSKER:
 - 12 Q So let's see if you can answer it again.
 - 13 Is the screen on the Bio-Rad Multi UV Wavelength
 - 14 Detector, is that electronics?
 - 15 A As an isolated element, it is electronics, 10:18:49
 - 16 yes.
 - 17 Q Is it an electrical component?
 - 18 A It is an electrical component, yes.
 - 19 Q And that electrical component, is that
 - 20 internal or external to the housing of the machine? 10:19:03
 - 21 A Well, I, as not an expert in this area,
 - 22 assume that the surface of the screen is -- is not
 - 23 an electrical component. What's behind it is an
 - 24 electrical component.
 - Q Do you know whether any of the electrical 10:19:22
 Page 37

173.

- 15 Q Really? So you think the claim is -- you 10:26:32
- 16 think it's fine to have electronics and electrical
- 17 components external to the housing of the machine?
- 18 A For example, the conductivity cell that
- 19 you've already pointed to is external to the
- 20 machine. 10:26:46
- 21 Q I know that.
- 22 A And if you consider that the -- that the
- 23 electrodes of the conductivity cell are electronics
- 24 or electronic, or whatever you want to -- however
- 25 you want to define that, then that's external to the 10:26:58
 Page 44
 - 1 machine, yes.
 - 2 Q And the light source is an electrical
 - 3 component, and that would be external to the housing
 - 4 of the machine, correct?
 - 5 A It might be. I didn't determine where the 10:27:08
 - 6 light source was.
 - 7 Q Well, let's assume that the light source is
 - 8 contained within -- within that housing that you
 - 9 point to that says fluidics section. Do you see
- 10 that? 10:27:28
- 11 A Okay.
- 12 Q If it's contained within that, that would
- 13 be an electrical component which is external to the
- 14 housing of the machine, correct?
- 15 MR. NISHIMOTO: Objection. Form. 10:27:37
- 174. 16 THE WITNESS: Yes, I think so.

- 175. In fact, Dr. Scandella testified at p. 48 of his deposition that the UV module, which was exhibit 41 to his report contained electronic components on the same side of the panel member as the fluidics.
 - The module shown in Figure 41 --12
 - 13 Yes.
 - Q -- in your declaration has electrical 14
 - 15 components on the same side of the panel as the 10:30:5
 - 16 fluidics section, correct?
 - Right.
 - 176.
- I reproduce Fig. 41 along with Dr. Scandella's annotations of the figure and a 177. short paragraph from his report describing the figure below:

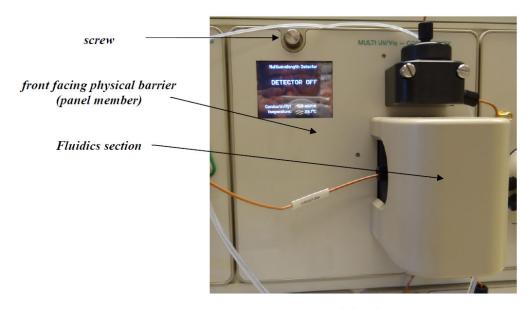


Fig. 41

42. The panel member also provides for attachment of the modular component to the liquid handling panel. Specifically, the panel member contains a screw or screws (shown in Figure 41 above) which, when tightened, attach the modular component to the liquid handling panel (shown in Figure 42 below). See also NGC Instrument Guide v. 1 pp. 187-188

178.

179. Given the statements of the inventors, the testimony of Dr. Scandella and the images of the UV and conductivity detector, one of ordinary skill in the art could not conclude that the UV/Conductivity modules have: fluidics and non fluidics sections, that they have a panel member that separates the fluidic from non fluidic sections, that they have a liquid handling panel that separates fluid from non fluidics, that the non fluidic electronic section is internal to the housing when inserted into the respective cavity of the housing. I have confirmd in conversations with Joe Hilario that each of the Bio-Rad UV/Conductivity modules (eg single and multi-wavelength) have electronics outside the housing and on the same side of the panel member as the fluidics section. For example,

. For at least all these reasons, the UV/Conductivity module cannot meet this claim element. I did not see any other sensor unit that Dr. Wereley relied on to meet the sensor limitation, but even if he did, all the sensor units that Bio-Rad can use in the accused systems contain the same arrangement as the UV/Conductivity modules. There are electronics that are part of the modules that are on the outside of the housing and on the same side of the panel member as the fluidics. Thus, such sensor units would not meet the limitations of the claims for the reasons already described previously for the liquid handling units. Moreover sensor units such as the PH detector contain additional electronics that are part of the module, external rather than internal to the housing and on the same side of the panel member as the fluidics. The PH detector has an electrode that is placed in contact with fluid and is part of the module. Thus the PH detector module cannot meet this limitation of claim 1 or the limitations of claim 5 below.

- 180. Many of the subsequent claims contain the same limitations and whether or not specifically stated, the arguments made thus far are specifically incorporated and become part of the argument for the subsequent limitations as well.
 - 8. Dependent Claim 5: "further comprises a pH electrode that is external to the housing"
- 181. Claim 5 depends from claim 1, and requires that the recited liquid chromatography system "further comprises a pH electrode that is external to the housing."
- 182. I have discussed why this element is not met with respect to my discussion of element 1.e. and the last element discussed above for claim 1(m). I incorporate those discussions fully for this element. Therefore, the "pH electrode" is not "external to the housing" as required.
 - 9. Dependent Claim 6: "that the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve"
- 183. Claim 6 depends from claim 5, and requires "that the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve."
- 184. I have discussed why this element is not met with respect to my discussion of element 1.e. and the other elements of claim 1. All of the fluid handling modules in the Bio-Rad accused devices are structured in the same way as the pump and inject valves I discussed with claim 1 and cannot meet the elements of that claim for the same reasons. Further, as discussed above with regard to element 1(m) all of the sensor units or modules used in the Bio-Rad accused devices have the same general structure. In addition to the types of electronics identified for the fluid handling units, all the sensor units have further electronics outside the housing which are used to perform the sensing function.

- 10. Dependent Claim 7: "the pH electrode is connected to a pH valve formed as an interchangeable modular component"
- 185. Claim 7 depends from claim 5, and requires that "the pH electrode is connected to a pH valve formed as an interchangeable modular component."
- 186. For the reasons stated previously with respect to the claims discussed already, a pH valve with an electrode attached in the Bio-Rad accused products cannot infringe.
 - 11. Dependent Claim 8: "the pH valve includes an integrated flow cell for in-line monitoring of pH levels"
- 187. Claim 8 depends from claim 7, and requires that "the pH valve includes an integrated flow cell for in-line monitoring of pH levels." See claim 7.
 - 12. Dependent Claim 15: "the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve."
- 188. Claim 15 depends from claim 1, and requires "the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, or an outlet valve."
- 189. For the reasons stated previously with respect to the claims already discussed, any of these modules in the Bio-Rad system cannot meet the limitations of this claim.
 - 13. Element [17.v]: "a panel member arranged to separate a fluidics section from a non-fluidics section"
- 190. Element [17.v] of the '420 patent requires "a panel member arranged to separate a fluidics section from a non-fluidics section."
- 191. I have discussed why this element is not met with respect to my discussion of element 1(e) through 1.h. I incorporate those discussions fully for this element.
 - 14. Element [17.ix]: "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when

inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing"

- 192. See corresponding element of claim 1 which I incorporate herein. Element
 - 15. Element [17.xi]: "wherein each interchange modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"
- 193. Element [17.xi] of the '420 patent requires "each interchange modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."
- 194. I have discussed why this element is not met with respect to my discussion of element 1.k. I incorporate those discussions fully for this element.
- 195. In summary, a person of ordinary skill in the art would <u>not</u> read this limitation to mean that the "modular fluid handling unit" cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.
- 196. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.
 - 16. Element [17.xiii]: "wherein said housing is adapted to accommodate at least one pump, at least one sensor unit, and at least two fluid control valves of different configurations, of which at least two of the

pump, the sensor unit, and the fluid control valves are interchangeable modular components"

- 197. Element [17.xiii] of the '420 patent requires "said housing is adapted to accommodate at least one pump, at least one sensor unit, and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components"
- 198. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.

17. Dependent Claim 22

199. Claim 22 is analogous to dependent claim 5. See VII.A.8.

18. Dependent Claim 23

200. Claim 23 is analogous to dependent claim 6. See VII.A.9.

19. Dependent Claim 24

201. Claim 24 is analogous to dependent claim 7. See VII.A.10.

20. Dependent Claim 25

- 202. Claim 25 is analogous to dependent claim 8. See VII.A.11.
 - 21. Element [27.e]: "a panel member arranged to separate a fluidics section from a non-fluidics section"
- 203. Element [27.e] of the '420 patent requires "a panel member arranged to separate a fluidics section from a non-fluidics section."
- 204. I have discussed why this element is not met with respect to my discussion of element 1.h. I incorporate those discussions fully for this element.
- 205. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] for this element. In

summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).

- 22. Element [27.i]: "wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing"
- 206. Element [27.i] of the '420 patent requires "wherein the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."
- 207. I have discussed why this element is not met with respect to my discussion of elements 1(e), 1(f) and 1(h). I incorporate those discussions fully for this element.
- 208. The NGC System does not infringe this element because the alleged housing lacks the underlined portions of the claim element: "the housing comprises a liquid handling panel with at least four component receiving positions arranged in a two dimensional array and

adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."

- In summary, the failure of proof for this element is most easily demonstrated with 209. reference to the inventors' discussion of the Hess reference. As discussed with respect to elements 1(e) and 1(f), in the Hess reference, each module had electronics sealed in a box and fluidics visible from a side that one can consider the front of the box. The inventors pointed out that what the examiner was considering the modules also had a single electrical connection exiting the back of the box. See e.g. ¶ 91-93 herein. For this reason, they concluded that Hess did not have a non fluidics section internal to said housing and a fluidics section external to said housing. There is no way for one of ordinary skill in the art to distinguish the arrangement in Hess that the inventors said was outside the scope of their invention with the arrangement in the accused modules. In the accused modules, there are electronics outside the housing. Those electronics cannot be a section that is distinct from the electronics that are inside the housing, just like the single electronic connection in Hess was not distinct from the electronics contained in the sealed boxes. Because the electronics inside the sealed boxes in Hess, that the examiner considered a housing did not constitute a non fluidics section that was internal to said housing when inserted, one of ordinary skill in the art could not also consider the electronics that Dr. Wereley considered to be embedded in the panel member to be a non fluidic section that is distinct from the electronics that are inside the housing in the Bio-Rad accused modules.
- 210. Therefore, Dr. Wereley has failed to meet his burden to establish the existence of this element in the accused fluid handling modules.
 - 23. Element [27.k]: "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"

- 211. Element [27.k] of the '420 patent requires "each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."
- 212. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.
- 213. In summary, a person of ordinary skill in the art would <u>not</u> read this limitation to mean that the "modular fluid handling unit" cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.
- 214. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.
 - 24. Element [27.m]: "wherein said housing is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are interchangeable modular components"
- 215. For the reasons stated previously the sample inject module and the two system pump modules are not interchangeable modular components because the interchangeable modular components of claim 1 need to have the fluidics and non fluidics sections of elements 1.e and 1.f as well as the separation requirements of elements 1 (h, i, j) and the independent

operations requirements of element 1.k and identification requirement of 1(l) which the sample inject module and the two pump modules do not have as described previously which I incorporate herein.

- 216. In summary, with respect to the UV module that Dr. Wereley points relies on to satisfy this claim element, he identifies a sensor unit, but neither the Bio-Rad single or multi-wavelength UV detectors qualifies as interchangeable modular units that can satisfy this element because neither has the required fluidics and non fluidics sections, a panel member for separating those sections, and a liquid handling panel for separating those sections, nor does either satisfy the requirement that the electronics be internal to the housing when inserted.
- 217. One of ordinary skill in the art reading the file history, specification and claims would conclude that the Bio-Rad single and multi-wavelength detectors are not interchangeable modular units as required by the claims. In fact, the inventors addressed this very type of component and unequivocally stated that such a detector did not come within the claims of its invention.
 - 25. Dependent Claim 30: "the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component"
- 218. Claim 30 depends from claim 27, and requires that "the system further comprises a pH electrode that is external to the housing, and wherein the pH electrode is connected to a pH valve formed as an interchangeable modular component."
- 219. I have discussed why this element is not met with respect to my discussion of element 1.e and claim 5. I incorporate those discussions fully for this element. Therefore, the "pH electrode" is not "external to the housing" as required.

B. Non-Infringement of the '589 Patent

- 1. Element [1.d]: "wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array"
- 220. Element [1.d]: "wherein the housing unit comprises on one external side of the housing unit a plurality of receiving positions, each receiving position adapted to receive the modular fluid handling units therein such that a fluid handling section thereof is on the external side of the housing unit, the receiving positions being arranged in a two dimensional array."
- 221. I have discussed why there is not fluid handling section in the accused products with respect to claim 1 of the 420 paten which I incorporate fully herein.
 - 2. Element [1.g]: "wherein each modular fluid handling unit . . . includes a CPU for independently performing fluid control operations in response to instructions over a system BUS"
- 222. Element [1.g] of the '589 patent requires "wherein each modular fluid handling unit . . . includes a CPU for performing fluid control operations independently irrespective of the location within the housing unit."
- 223. See discussion for corresponding element of claim 1 of the 420 patent incorporated herein.
 - 3. Element [6.f]: "each modular fluid handling unit includes a CPU for performing fluid control operations independently irrespective of the location within the housing unit"
 - 224. See corresponding element of claim 1 of the 420 patent incorporated herein.
 - 4. Dependent Claim 7: "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units"

- 225. Claim 7 depends from 6, and requires that the "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit, and the fluid control valves are freely arrangeable modular fluid handling units."
- 226. I have discussed why this element is not met with respect to my discussion of claim 1 and element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.
 - 5. Dependent Claim 8: "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit and the fluid control valves are arranged as modular fluid handling units"
- 227. Claim 8 depends from 1, and requires that the "housing unit is adapted to accommodate at least one pump, at least one sensor unit and at least two fluid control valves of different configurations, of which at least two of the pump, the sensor unit and the fluid control valves are arranged as modular fluid handling units."
- 228. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.
 - 6. Dependent Claim 9: "the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve"
- 229. Claim 9 depends from claim 8, which in turn depends from claim 1, and requires that "the at least two fluid control valves include an injection valve, a column valve with integrated pressure sensors, a quaternary valve, an inlet valve, a sample inlet valve, a pH valve, and an outlet valve."

- 230. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.
 - 7. Dependent Claim 13: "the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit"
- 231. Claim 13 depends from claim 1, and requires that "the automatic liquid chromatography system further comprises a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit."
- 232. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.
 - 8. Dependent Claim 14: "the pH valve includes an integrated flow cell for in-line monitoring of pH levels"
- 233. Claim 14 depends from claim 13, and requires that "the pH valve includes an integrated flow cell for in-line monitoring of pH levels."
- 234. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.
 - 9. Dependent Claim 21: "the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit"
- 235. Claim 21 depends from claim 20, and requires that "the fluid handling section of the modular fluid handling unit is sealed from an internal side of the housing unit when fitted in a receiving position of the housing unit."

- 236. I have discussed why this element is not met with respect to my discussion of element 1.h of the '420 patent. I incorporate those discussions fully for this element.
- 237. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).
 - 10. Dependent Claim 24: "a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit"
- 238. Claim 24 depends from claim 6, and requires "a pH electrode that is external to the housing unit, and wherein the pH electrode is connected to a pH valve arranged as a modular fluid handling unit."

239.

11. Dependent Claim 25: "the pH valve includes an integrated flow cell for in-line monitoring of pH levels"

- 240. Claim 24 depends from claim 24, which depends from claim 6, and requires "the pH valve includes an integrated flow cell for in-line monitoring of pH levels."
- 241. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.
 - 12. Dependent Claim 26: "the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer"
- 242. Claim 26 depends from claim 6, and requires "the modular fluid handling units include two double piston pumps, one injection valve for injecting a sample onto a column connecting a flow path of the liquid chromatography system, a UV monitor, and a mixer."
- 243. I have discussed why this element is not met with respect to my discussion of element 1.e and dependent claims 5-6 of the '420 patent. I incorporate those discussions fully for this element.

C. Non-Infringement of the '590 Patent

- 1. Element [1.b]: "interchanging at least two of the interchangeable modular components in a housing unit comprising at least four component receiving positions arranged in a two dimensional array, so as to allow for modification of the liquid chromatography fluid flow path among the at least four interchangeable modular components"
- 244. Dr. Wereley has not shown that this element was met. I understand that in order to infringe this claim, which is a method claim the steps claimed need to have been performed. Additionally, they need to have been performed in the United States and after the 590 patent issued on January 18, 2017. I see no such proof offered in Dr. Wereley's report.
- 245. At paragraphs 491-507, Dr. Wereley states that he has seen videos of people changing modules. But he does not establish in his report where this alleged changing is

occurring, and he does not establish the date on which the alleged changing occurred. Further he does not establish that the fluid flow path actually changed. I understand that this element requires that fluid be flowed through the system and that the path be different than the path that existed before the change. I do not see evidence of that in Dr. Wereley's report.

- 246. Moreover, Dr. Wereley's claim, citing testimony from Mr. Chapman at ¶ 501, that Bio-Rad changes the modules on customers machines approximately of the time does not establish infringement of this element. First, the testimony from Mr. Chapman stated that he guessed changes were made in of the occasions where he was present helping customers. That does not mean that Mr. Chapman is present at 100% of customer sites and thus his guess of equates to of Bio-Rad customers performing this operation. Second, Mr. Chapman did not testify that the times where he was present and customers made changes were done in the United States and after January 18, 2017. Last, Mr. Chapman did not testify that the fluid flow patent changed. Moving a module to a different position does not necessarily change the flow path. For example if one has two pump modules, module one can be placed where module 2 was, and a new pump can then be placed where module one was.
- 247. Additionally, Dr. Wereley cites as proof the fact that Discover machines are shipped with no modules in them and then are populated with modules. But placing a module in a machine with no modules does not satisfy the claim. Rather, modules must be taken out, and the flow path in situation one and situation two, (the interchanged modules) must be different. That is not possible when the first situation had no flow path at all because it had no modules.
 - 2. Element [1.c]: "wherein each of the at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit"

- 248. Element [1.c] of the '590 patent requires "wherein each of the at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit."
- 249. The NGC System does not infringe claim 1 of the '590 patent because it lacks "at least four interchangeable modular components comprises a CPU unit for independently performing fluid control operations in response to instructions from a system controller when installed in a component receiving position of the housing unit."
- 250. I have discussed why this element is not met with respect to my discussion of elements 1.k of the '420 patent. I incorporate those discussions fully for this element.
- 251. In summary, a person of ordinary skill in the art would <u>not</u> read this limitation to mean that the "modular fluid handling unit" cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.
- 252. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.

3. Claims 2 and 3, Flow path shortened

253. None of the evidence that Dr. Wereley cited shows that even if modules are interchanged, the flow path is shortened. The same is true for the evidence he cited for claim 3. Thus, he failed to meet his burden on these claims.

4. Claims 10 and 12

- 254. Dr. Wereley has not met his burden to establish infringement of these claims. While he says the steps claimed could be done, he points to nothing where these steps were actually done in the United States after Jan. 18, 2017. That is what is necessary to establish infringement of this method claim. For this reason, he has not met his burden to show infringement.
 - 5. Element [13.h]: "comprising a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit"
- 255. Element [13.h] requires "the at least two interchangeable modular fluid handling units ... compris[e] a CPU that allows independent fluid control operations in response to instructions from the main controller when installed in the component receiving position of the housing unit"
- 256. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.
- 257. In summary, a person of ordinary skill in the art would <u>not</u> read this limitation to mean that the modular component's cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

- 258. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.
 - 6. Claim 14 "adding an expansion housing unit that includes a plurality of component receiving positions, each component receiving position being adapted to receive the at least one interchangeable modular fluid handling unit, and placing at least one additional interchangeable modular fluid handling unit in one of the component receiving positions in the expansion housing"
- 259. While Dr. Wereley states that the elements of these claims could be done, he does not cite evcidence showing that the expansion housings were used. Nor does he show any use in the United States after January 18, 2017. He has therefore failed to meet his burden to establish infringement.
 - 7. Claim 17: "the CPU allows for automatic identification by the liquid chromatography system upon placement in a component receiving position of similar size and shape"
- 260. I do not agree with Dr. Wereley that the CPU does need to do the identification. In any event, the testimony that Dr. Wereley cites and his conclusion about infringement of this claim are inconsistent with the conclusions he reached in corresponding claims of the 420 patent where he stated that the MCU was doing the identification. I incorporated the arguments I made with respect to that claim. Moreover as with the other claims in this patent he has not shown that the method was actually performed in the U.S. at the proper time.
 - 8. Claim 18: "the at least two interchangeable modular fluid handling units are connected to the system by a system BUS"

261. Dr. Wereley has not provided any evidence showing that this step was performed in the U.S. at the proper time to establish infringement. Therefore he has failed to meet his burden of proof.

D. The '591 Patent

- 1. The NGC System Does Not Infringe Claim 9 of the '591 Patent at Least Because it Lacks Several Elements in Claim 1 from Which it Depends
- 262. Claim 9 depends on claim 1. I note that claim 1 of the '591 patent is nearly identical to claim 1 of the '420 patent. Thus, I incorporate my analysis of claim 1 of the '420 patent.

(a) Element [1.v]: an external fluidics section

- 263. Element [1.v] requires "an external fluidics section."
- 264. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

(b) Element [1.vi]: an internal non fluidics section

- 265. I have discussed why this element is not met with respect to my discussion of element 1.f of the '420 patent. I incorporate those discussions fully for this element.
 - (c) Element [1.viii]: "a panel member arranged to separate the fluidics section from the non-fluidics section"
- 266. Element [1.viii] of claim 1 of the '591 patent requires "a panel member arranged to separate the fluidics section from the non-fluidics section."
- 267. The NGC System does not infringe claim 9 at least because it lacks "a panel member arranged to separate the fluidics section from the non-fluidics section," as claimed.
- 268. I have discussed why this element is not met with respect to my discussion of element 1.h of the '420 patent. I incorporate those discussions fully for this element.

- 269. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] of the '420 patent for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent **not on either side of a panel."**)(emphasis added).
 - (d) Element [1.ix]: "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing"
- 270. Element [1.ix] of claim 1 of the '591 patent requires "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the fluidics section is external to the housing and the non-fluidics section is internal to the housing."
- 271. The NGC System does not infringe claim 9 at least because it lacks "wherein the housing comprises a liquid handling panel with two or more component receiving positions adapted to receive said interchangeable modular components such that, when inserted, the

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fluidics section is external to the housing and the non-fluidics section is internal to the housing," as claimed.

- 272. I have discussed why this element is not met with respect to my discussion of elements 1.e and 1.f of the '420 patent. I incorporate those discussions fully for this element.
 - (e) Claim [1.xi]: "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus"
- 273. Dependent claim [1.xi] requires "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus."
- 274. The NGC System does not infringe claim 9 at least because it lacks "wherein each interchangeable modular component includes a dedicated CPU unit allowing the interchangeable modular component to independently perform operations in response to instructions over the system bus," as claimed.
- 275. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.
- 276. In summary, a person of ordinary skill in the art would <u>not</u> read this limitation to mean that the modular component's cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.

- 277. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.
 - 2. Dependent Claim 26: "the pH electrode is connected to a pH valve formed as an interchangeable modular component"
- 278. Claim 26 depends from claim 12, and recites that "the pH electrode is connected to a pH valve formed as an interchangeable modular component."
- 279. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.
 - 3. Dependent Claim 27: "the pH valve include[] an integrated flow cell for in-line monitoring of pH levels"
- 280. Claim 27 depends from claim 26, and further requires that "the pH valve include[] an integrated flow cell for in-line monitoring of pH levels."
- 281. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

E. Non-Infringement of the '124 Patent

- 1. Element [16.h]: "a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel."
- 282. Element [16.h] requires "a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel."

- 283. The NGC System does not infringe claim 16 at least because it lacks "a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel," as claimed.
- 284. I have discussed why this element is not met with respect to my discussion of element 1.h of the '420 patent. I incorporate those discussions fully for this element.
- 285. The NGC System does not infringe this element because the NGC System does not include "a panel member arranged to separate the fluidics section from the non-fluidics section" as claimed. I incorporate my discussion of elements [1.e] and [1.f] of the '420 patent for this element. In summary, the electronics in the housing are not a separate non-fluidics section from the electronics Dr. Wereley describes as embedded in the panel member. "Embedding" as shown with the arrangement of Bergstrom does not create separate sections. There is no way to square the representations the inventors made about Mourtada, Bergstrom and Hess with respect to separation, with the arrangement in the Bio-Rad accused modules that have electronics adjacent to and on the same side of the panel member as the fluidics. At a minimum, the electronics that Dr. Wereley describes as being embedded in the panel member are the fluidics in the Bio-Rad accused modules, which are not on "either side" of the panel member as the inventors said they must be. Ex. G at 1451 ("The detector module 10 of Fig. 10 illustrates that fluid and electrical parts are adjacent not on either side of a panel.") (emphasis added).
 - 2. Element [16.i]: "wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing"
- 286. Element [16.i] requires "wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing."

- 287. The NGC System does not infringe claim 16 at least because it lacks "the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing" as claimed.
- 288. I have discussed why this element is not met with respect to my discussion of elements 1.e and 1.f of the '420 patent. I incorporate those discussions fully for this element.
 - 3. Element [16.j]: "respective non fluidics sections are internal to the housing"
- 289. Element [16.j] requires that the "respective non fluidics sections are internal to the housing."
- 290. I have discussed why this element is not met with respect to my discussion of element 1.f of the '420 patent. I incorporate those discussions fully for this element.
 - 4. Dependent Claim 20: "wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus"
- 291. Element [20.c] requires "wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus."
- 292. The NGC System does not infringe Claim 20 at least because it lacks "wherein each of the interchangeable modular components includes a dedicated CPU unit allowing each of the interchangeable modular components to independently perform operations in response to instructions over the bus" as claimed.
- 293. I have discussed why this element is not met with respect to my discussion of element 1.k of the '420 patent. I incorporate those discussions fully for this element.

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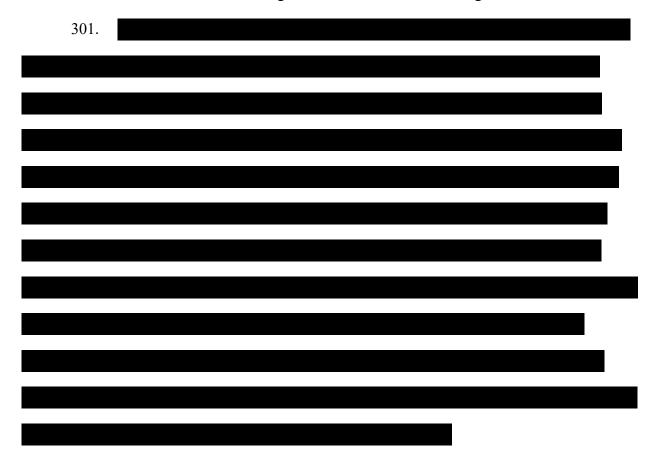
- 294. In summary, a person of ordinary skill in the art would <u>not</u> read this limitation to mean that the modular component's cpu does nothing more than take the signal that the master control unit has sent and forward it. For example, if the master control unit sent out a signal that would deliver a certain voltage or current to a module to make it operate at a certain level (*e.g.*, A high or low signal), one of ordinary skill in the art would <u>not</u> read the specification to mean that the CPU would take an instruction and merely create that same current or voltage or simply translate that instruction into a different format.
- 295. Rather, one of ordinary skill in the art would understand the passage in the specification relating to the use independent operation of the CPU to mean that a signal is received from the master control unit and then the CPU does something above and beyond what that signal indicates and what the MCU would have done on its own, something that is independent of the signal the CPU sent.
 - 5. Dependent Claim 28 "the system includes two double piston pumps, one injection valve for injecting sample onto a column connecting to the flow path of the liquid chromatography system, a UV monitor, and a mixer"
- 296. Claim 28 depends from claim 16, and further requires that the system recited there comprise "two double piston pumps, one injection valve for injecting sample onto a column connecting to the flow path of the liquid chromatography system, a UV monitor, and a mixer."
- 297. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.
 - 6. Dependent Claim 30: "further includes a pH-valve with an integrated flow cell for in-line monitoring of pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients"
- 298. Claim 30 depends from claim 28, which in turn depends on claim 16, and requires that the system "further includes a pH-valve with an integrated flow cell for in-line monitoring of

pH levels, and a quaternary valve for automatic buffer preparation and formation of quaternary gradients."

299. I have discussed why this element is not met with respect to my discussion of element 1.e of the '420 patent. I incorporate those discussions fully for this element.

IX. NON-INFRINGING ALTERNATIVES

300. I have also been asked to opine on the existence of non-infringing alternatives and the relative difficult in creating a non infringing alternative by modifying the accused NGC products. In summary, it is my opinion that non-infringing alternatives, such as the Bio-Rad DuoFlow, exist. That chromatography system was the predecessor to the NGC. Moreover, modifications to the NGC could be designed which would avoid infringement.



302. In this regard, Dr. Wereley has his analysis backwards. He states that not having a CPU on each module would result in increased cost and complexity and it is not clear that it

HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS' EYES ONLY

DATED: October 21, 2020

Bruce K. Gale, Ph.D.

EXHIBIT 3

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1	IN THE UNITED STATES DISTRICT COURT
2	IN AND FOR THE DISTRICT OF DELAWARE
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5	GE HEALTHCARE BIO-SCIENCES : CIVIL ACTION AB, GE HEALTHCARE :
6	BIO-SCIENCES CORPORATION, : and GENERAL ELECTRIC :
0	COMPANY, :
7	:
	Plaintiffs, :
8	:
9	vs. :
9	BIO-RAD LABORATORIES, INC., :
10	:
11	Defendant. : NO. 18-1899-CFC
12	
13	Wilmington, Delaware
13	Thursday, May 14, 2020
14	10:30 o'clock, a.m.
	***Telephone conference
15	
16	DEFORE WAYARING GALVE GARVALLY W. G. D. G. T.
17	BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.
1 /	
18	
	APPEARANCES:
19	
20	SHAW KELLER LLP
0.1	BY: JOHN W. SHAW, ESQ.
21	
22	-and-
23	
24	
25	Valerie J. Gunning Official Court Reporter

Case 1:18-cv-01899-CFC-SRF Document 194 Filed 12/22/20 Page 109 of 177 PageID #: 96

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that.

in the claim

the fluidics side.

doesn't say anything about what is going to be in the fluidics section. It's just saying, hey, look, we have a non-fluidics section. Your prior art does not teach a non-fluidics section. That's the distinction. So that can't arise to a clear and unmistakable disavowal because they are talking about two different things.

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What they are saying is, hey, look, you need to move all of the electronics into the, into this non-fluidics section. All they were saying is like, look, what you are pointing to as a non-fluidics section, it's not a non-fluidics section because it has electronic components in

THE COURT: But it says, look at slide 59. In Bergstrom, the opposite is taught. Fluid and non-fluidic parts are together, and you are saying, no. You know, because of the definition you want me to adopt, you want a one-way street. You don't want to have reciprocity, so you want to have non-fluidic as defined as not including fluidic, but fluidic sections not defined as barring non-fluidics, and yet --

MR. MILLER: And -- I'm sorry. Go ahead.

THE COURT: And then to overcome the objection, you say in Bergstrom the fluid and the non-fluidic parts are together, which is what you want to have now in the fluidics section.

9 interrupting, but did he say page 1477? 10 THE COURT: Yes. 11 MR. BILSKER: Okay. 12 MS. SKLENAR: Your Honor, if I can just 13 interrupt for a second. This is Ms. Sklenar. 14 If I could propose a compromise position in 15 order to address some of the comments that Your Honor has 16 made, but also try to get at the issue that I think we're 17 concerned about. 18 THE COURT: Okay.

MS. SKLENAR: If we could look at Figure 4A,

I can give you my proposed compromise with reference to

right, because electronics components are explicitly recited

no electronic components in the fluidics section. They

would be crazy to do so because the specification literally

describes several examples where there are electronics on

MR. BILSKER: Your Honor, I apologize for

So that's what they are talking about, there's

THE COURT: Okay.

23 MS. SKLENAR: In light of Your Honor's comments, 24 we could agree to construction where there needs to be a 25 fluidics section with only fluidics, and that there needs to

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MR. MILLER: Well, but the entire discussion is about what the Examiner was saying was a non-fluidics section.

So the non-fluidics section --

THE COURT: Show me where it is clear from the prosecution history they are only talking about a "non-fluidic section."

MR. MILLER: Give me a moment, Your Honor.

9 (Pause.)

10 MR. MILLER: Are you looking at Exhibit D?

THE COURT: Yes, I'm there.

12 MR. MILLER: I think if you go to 1477. In the 13

heat of the moment, this is all I can do right now.

14 THE COURT: Okay. I'm there.

15 MR. MILLER: At the top there it says, wherein

this -- one, two, three, four, five lines down. 16

THE COURT: Okay.

MR. MILLER: It says, wherein the liquid handling panel, the objects are arranged such that each external fluidics of the unit is separated from its respective modular section by the liquid handling panel. It says it is not disclosed in the prior art.

23 So, and then they made a claim to say that the 24 fluidics section comprised electronics and electrical 25 components. And I would submit that that is support to us, be a non-fluidics section that can't have fluidics, but what

2 we're trying to preserve and carve out is this idea that

3 it's possible that there could be another section somewhere

4 on the module -- you know, not in the fluidics section, but

5 somewhere else. For example, if we look at Figure 4A and

6 you see 28, which was the panel number, what we're trying to

7 prevent is someone from saying, we don't infringe this claim

8 if we have, say, stuck in the panel member 28 some lights.

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So they'll say, well, there's electronics there and it's not

10 in the non-fluidics section.

> So if Bio-Rad's construction is adopted, which says all electronics for the module have to be in the non-fluidics section, they would basically be excluding that configuration from the claim where you got electronics

15 elsewhere but they are not in the fluidics section.

16 THE COURT: But, see, actually, this is very 17 interesting that you propose this. If you recall, I

18 actually led with the questions that exactly went to this

19 issue, because my first question was about, can you have, do 20 you have to have electronic components in the fluidics

21 section, because I think it's clear that the written

22 description allows for there to be non-fluidic components

23 external to the non-fluidics section. They just, and I

24 think this is a key, they just can't be in the fluidics

25 section.

Page 94 to 97 of 105

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1 So basically, what you are saying makes sense to 2 me, I think. Let's hear from Bio-Rad says. 3 MR. BILSKER: Absolutely not, Your Honor. 4 THE COURT: Why not? 5 MR. BILSKER: Because again, it begs the 6 question. What is a section? They want to say you can have 7 a fluidics section, because if I have -- if I have this 8 fluid line here, I will draw a circle around this fluid line 9 and I'm going to call that a fluidics section, and then if I 10 have more fluidics on the side and they're next to 11 electronic parts, I'm not going to call those part of the 12 fluidics section. Those are a different section. And that 13 is completely inconsistent with the representation that they 14 made about Hess. 15 And let me just -- the reason I asked whether he 16 was pointing to page 1477 is because 1477 is talking about 17 Mourtada. It's not talking about Bergstrom. 18 And if we go back to the slides on Hess --19 THE COURT: No, no. Don't go there yet. Let's 20 just finish up. You see, look, if you've got --21 MR. BILSKER: Again, that's not what they 22 claimed. 23 THE COURT: Just hold on a second, please. I 24 mean, what I understand the compromise is, essentially, if

1 just not what they said during the prosecution. The section 2 was defined as all parts of that type, and that's again, if 3 we go through slide 58, 59 --

4 THE COURT: But I guess what I'm getting at it 5 is, I think, GE, would you agree then, would you agree to 6 Bio-Rad's construction?

MS. SKLENAR: No, because our issue with their construction is that it says essentially all electronics for the module, for the entire module have to be in a non-fluidics section. And, again, that would allow --

11 THE COURT: Fair enough. So what if it just 12 said though, a section -- yes. I mean, you know, here's 13 where I am. I will just tell you right now.

So I'm not able to accept GE's position that on one hand a non-fluidic section can contain fluidics. On the other hand, a fluidics section cannot contain non-fluidics. On the other hand, the patent uses the indefinite article, so it contemplates one or more sections, and the Federal Circuit has said, understandably, that the indefinite article does not mean all.

So that is what I find problematic about Bio-Rad's construction, is they want to say all the fluidic components.

24 MS. SKLENAR: Yes. I apologize. 25

THE COURT: That's all right. You know, but GE,

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section, there can't be any fluidics in it, and a fluidics section would mean there's no non-fluidics in it.

you agree with Bio-Rad, that if you have a non-fluidics

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But could there be, in addition to those two sections, a third section, and you could have a mix. And as I look at claim 1, for instance, of the '591 patent, it has an external fluidics section. It has to have one. It has to have an internal non-fluidics section. So both of those sections would have to exist and would have to have in one case, the fluidics section, no non-fluidic component. In the second case, the non-fluidic section could not have any fluidic component.

And then it has to have a separate section, which is something distinct and different and is not within those two sections, and Bio-Rad here is saying you can't live with that.

MR. BILSKER: Absolutely not. Again, it begs the question. What is the section at that point? So I have a module and I have an outside part of it and I'm going to split it up into little, little piles, and I'm going to say, hey, I've actually got 45 different sections here on this module, 45 different sections on the outside. You know, I don't -- there's a bunch of electronics, but they're all on the top half. So because they're on the top half, I'm going to call only the bottom half my fluidics section and I'm not

going to call the top half my fluidics section, and that's

you know, I can't live with the way you want to interpret 2

3 MS. SKLENAR: Yes. If we can put all of our 4 cards on the table.

THE COURT: Well, that's helpful.

MS. SKLENAR: The reason we're fighting about this is because Bio-Rad wants to argue for noninfringement that they have some electrical components like lights that are in the panel member, so neither of the sections we're talking about, the fluidics or non-fluidics, but are in the panel member.

So, for example, what we see in Figure 4A at 28,

THE COURT: But that is not before you. Right?

they want their construction so they can then turn around and say, we don't infringe because we don't have all of our electrical components in one section. And what we're submitting -- and, again, we are modifying our approach. We are willing to agree that a fluidics section cannot have electronics or electrical components, but what we can't live with is this notion that somehow you could get outside of

20 the scope of this claims by putting little lights in a 21 different section.

23 You kind of did an all-or-nothing in your proposal. I mean, 24 it seems to me you could have been more judicious in the proposal and then left this issue for trial and figure it 25

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out. So why don't we just step back and let's go with, I'm looking at page 94 of your brief where we've got the competing construction proposals for fluid handling section. Right? And you've got a section of the interchangeable fluid handling unit that includes fluidics components.

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So why don't you just change that to be consistent with your construction of a non-fluidic section and say that this would be a section of the interchangeable fluid of the interchangeable fluid handling unit that does not include electrical components.

MS. SKLENAR: And we're willing to do that, Your Honor. It's the all issue we can't live with.

THE COURT: Okay. But, you know, then that's fair and I think that's a legitimate complaint. So here's where I am. That's how I'm going to interpret these terms.

I'm going to interpret non-fluidics section to mean, "a section of the interchangeable fluid handling unit that includes electrical components and does not include fluidics components."

I'm going to construe a fluid handling section to mean, "a section of the interchangeable fluid handling unit that includes fluidics components and does not include non-fluidics components." And that seems to me to be the

I read the briefs carefully. I've articulated 2 the general basis of my rulings. I'm cognizant that there's 3 de novo review in the Federal Circuit, so that really no 4 matter what I say has really no consequence, but I 5 appreciate the briefing and the arguments of the parties 6 today. And if you will just submit that order that is 7 consistent with my rulings today within a week, I will sign 8 it forthwith. 9 Anything else from the plaintiffs? 10 MS. SKLENAR: Nothing, Your Honor. Thank you so

11 much for your time. 12 THE COURT: Anything from the defense? 13 MR. BILSKER: I was just curious about the

14 transcript, but I guess we can handle it. 15 THE COURT: What do you mean?

16 MR. BILSKER: Whether we would get the 17 transcript just to make sure that the order is consistent 18 with the transcript. I was having a little trouble writing 19 as quickly as you were speaking.

20 THE COURT: Well, let's actually, before we 21 leave, where is there any ambiguity in what I've ruled on in 22 your mind?

MR. BILSKER: I don't think there's ambiguity. I just didn't have the exact words that you said. I didn't get a chance to write them down exactly. Maybe my associate

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most reasonable construction. That is consistent with what I think were clear and unequivocal statements to distinguish this patent from Bergstrom and Hess, because the basis of the distinctions to the Patent Examiner were that this patent had two sections that, at least two sections, one is non-fluidic, one is fluidic, that are separated completely and that do not contain components of the other section.

That does not, however, preclude the possibility that there are other sections that are in the invention, and that's important because that is consistent with the use of the indefinite article, which is inconsistent with Bio-Rad's insistence that "all," either fluidic or non-fluidic components, are in the respective handling unit.

So that actually seems to me is the right result in this case and I'm going to construe then these last group of terms in that manner.

17 All right. Is there anything else for me to 18 construe?

19 MS. SKLENAR: Nothing from plaintiff, Your 20 Honor.

21 MR. BILSKER: Mr. Bilsker. None.

in today's telephone conference.

22 THE COURT: Okay. I'm going to ask the 23 plaintiff to submit within a week from today a written order 24 of the claim chart and the basis of my rulings are set forth

did. That's all I was saying. 2 THE COURT: No, that's fair. And, really, I

3 think the big point is, it is kind of the thing that 4 disturbed me from the beginning with the plaintiffs' 5 argument, is on those last two, the fluidics and the non-fluidics, I just interpreted it as far as I'm concerned

7 in a manner that's consistent, and I think that Bio-Rad even 8 agreed insofar as it being consistent. That's the big

9 distinction there.

> So, okay. If because of the current situation you need more time to get the order in, to get the transcript ready, that's fine, but at least as of now we'll set it for a week from today, and the obligation will be on plaintiffs to submit the proposed claim construction order. Okay?

16 Everybody have a great day. Stay safe. Thanks 17 very much. Bye-bye. 18

(Counsel respond, "Thank you, Your Honor.") 19 (Telephone conference concluded at 1:12 p.m.)

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EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC,

Plaintiffs C.A. No. 18-1899-CFC

Consolidated

v.

DEMAND FOR JURY TRIAL

BIO-RAD LABORATORIES, INC.,

HIGHLY CONFIDENTIAL

Defendant.

 $(\textbf{TECHNICAL}) - \textbf{ATTORNEYS'} \ \textbf{EYES}$

ONLY

OPENING EXPERT REPORT OF DR. BRUCE GALE



The History of Metrohm IC

First Metrohm IC, the 690	1987
Introduction of the Modular IC	1996
Introduction of the Compact IC	1999
Introduction of the Advanced IC 2003	
Introduction of the Professional IC	2007



The anniversary: 20 Years Metrohm IC

H. Schäfer 8 Metrohm

293. Notably, Metrohm shifted to a modular ion chromatography system design in 1996, only 9 years after releasing their first ion chromatography system in 1987 and 12 years before the priority date of the Asserted Patents. Metrohm discusses considerations any system designer would take into account in opting to go with the design choice of a modular system. For example, Metrohm explained that a "compact instrument with modular structure" is desirable and that customers would benefit from such a design. *See id.* at 10-11. Specifically, the modularity benefits the customer by providing: "High flexibility – the user gets a customized instrument," "The instrument can be updated for other applications," and "The customer is not paying for items he doesn't need." *Id.* at 13. And the compactness of it benefits the customer by providing: "All in one housing," "No numerous instruments to combine with a lot of different cables," and "Ready to use." *Id.* at 14.

C. The 2040 System

294. The ADI 2040 Process Analyzer ("2040 System") was developed by Applikon Analytical in the late 1990s. The ADI 2040 was marketed and sold by at least August 1999. Declaration of Thomas Koshy ("Koshy Dec.") ¶ 4. During his deposition, Metrohm witness Mr. Thomas Koshy testified that the 2040 System was released in 1999, and the sold-analyzer list discussed during the deposition shows the 2040 System was sold in the U.S. since 1999. Metrohm Tr. at 107:6-109:24; 154:7-12; Metrohm Dep. Exh. 7 (excerpted below).

Analyzers 1999-2008 Applikon Analyzers Confidential 7/8/2015 Consolidated 1999-2008

END-USER Code	PLACE	ANALYZER	Year Sold
customer 63	MN	ADI 2040	2003
customer 64	FL	ADI 2040	2003
customer 65	ОН	ADI 2040	2003
customer 66	TX	ADI 2040	2003
customer 67	LA	ADI 2040	2003
customer 68	NJ	ADI 2040	2003
customer 69	TX	ADI 2040	2001
customer 70	LA	ADI 2040	2001
customer 71	TX	ADI 2040	2001
customer 72	LA	ADI 2040	2001
customer 73	TX	ADI 2040	2001
customer 74	Canada	ADI 2040	2000
customer 75	NY	ADI 2040	2000
customer 76	TX	ADI 2040	2000
customer 77	LA	ADI 2040	2000
customer 78	NY	ADI 2040	2000
customer 79	ОН	ADI 2040	2000
customer 80	ОН	ADI 2040	2000
customer 81	NY	ADI 2040	2000
customer 82	LA	ADI 2040	2000
customer 83	CA	ADI 2040	1999
customer 84	TX	ADI 2040	1999
customer 85	OR	ADI 2040	2004
customer 86	AZ	ADI 2040	2007

Case 1:18-cv-01899-CFC-SRF Document 194 Filed 12/22/20 Page 116 of 177 PageID #: 8020

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- 295. No changes were made to the hardware in the 2040 System over the time period from 2002 to 2008. Metrohm Tr. at 154:13-19. The 2040 System is therefore prior art to the patents-in-suit at least under 35 U.S.C. § 102(b).
- 296. The 2040 System documentation I cite in this report thus describes the 2040 System that was first sold in August 1999. The ADI 2040 Process Analyzer brochure from September 2008 ("ADI 2040 Brochure") that describes the ADI 2040 Process Analyzer, was available for download at least as early as September 2008. Koshy Dec. ¶ 7.
- 297. The 2040 System "is a multipurpose wet chemical analyzer, that has been designed to offer flexibility and withstand the harshest environments" and "makes use of proven analytical techniques, like titration, colorimetry and dynamic standard addition with ion selective electrodes." (2040 Brochure at BRGE00001521.) The 2040 System includes a multitude of "wet part modules" that are used for automated liquid handling as shown below.



(*Id.* at BRGE00001521.)

298. The wet part or fluid handling sections of the modules are on the external side of the housing and include the blue colored tubing for carrying fluids, while the electronics sections of the modules and the electronics for the system is inside the housing as shown below.



(2040 Brochure at BRGE00001521-22; see also 2040 Manual at BRGE00003266-67. 120)

299. I have inspected and analyzed a 2040 System that I have in my laboratory. I also performed tests to show the 2040 System can deliver controlled fluid flow to and through a liquid chromatograph column and which I consider an automated liquid chromatography system capable of performing automated liquid chromatography. The tests are described in the test report, attached as Exh. 4. I recorded videos of these tests showing the 2040 System performing liquid chromatography. A video of the test conducted on November 12, 2016 is attached as Exh. 5 and a video of the test conducted on November 14, 2016 is attached as Exh. 6. An edited version of the video for the November 12, 2016 test is attached as Exh. 7, and an edited version of the video for the November 14, 2016 test is attached as Exh. 8. I may choose to rely on all or parts of these videos in my trial testimony

D. The 850 System

Although I cite to the version of the 2040 Manual labeled BRGE00003253, the same disclosures I rely on can be found in the version of the same document produced as BIO-RAD-000001, which was used as Exhibit 6 at the Metrohm deposition. See Metrohm Tr. at 102:11-105:25 (also testifying that there were no major hardware changes to the 2040 System from 2008 until 2015).

HIGHLY CONFIDENTIAL (TECHNICAL) – ATTORNEYS' EYES ONLY

DATED: September 14, 2020

Bruce K. Gale, Ph.D.

EXHIBIT 4

Test Report 11-14-16

We performed a chromatography separation of 5 food dyes simultaneously on the Applikon instrument. The separation was complete and appeared to be a baseline separation between the dyes. The separation results were also reproducible with the centers of each of the dyes eluting at the same times. Each test was performed on different days spanning an 11 day period. The results were also reproducible after switching the positions of two of the fluidic components within the Applikon instrument.

Instrument Programming Details

The goal of the programming was to reproduce the steps of a dye chromatography experiment. The shared stirrer for PBS and methanol mixing was the sole supply of fluid to the 5mL/min peristaltic pump that was pumping the elutant through the C18 chromatography column. Figure 1 shows all the various pumps, valves and stirrers that were programmed to perform the experiment, the names on the labels will be used throughout the programming description. All the programming was performed on the instrument using the built-in keypad and function buttons. Any pump or valve that is not labeled in the figure was not required for the chromatography experiments that we performed.

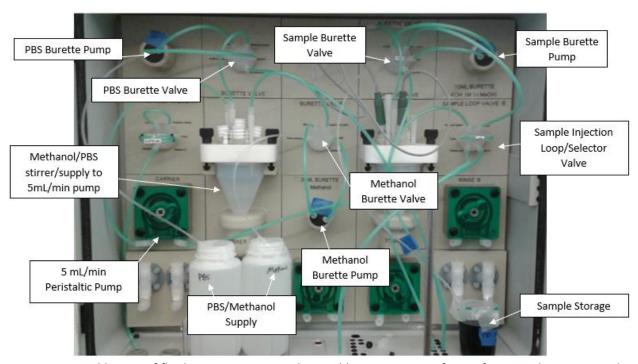


Figure 1. Initial layout of fluidic components in the Applikon instrument for performing chromatography in Tests A, B, and C.

The first step in the program was a flush of the sampling column using 100% methanol to ensure that all contaminants were flushed out of the column. To perform the flush 40 mL of methanol was pumped from the methanol supply into the stirrer/supply reservoir using the methanol burette pump. Due to the 20 mL capacity of the burette, this required the burette to fill and dispense twice. After the methanol was pumped into the supply reservoir, the 5mL/min peristaltic pump was switched on and the methanol was drawn from the reservoir and pumped to the sample injection valve which was set in the

"on" position. In the "on" position the fluid from the peristaltic pump bypasses the sample loop itself and flows straight into the chromatography column.

After pumping pure methanol through the column, the next step was to return the fluid in the column to 50% PBS. This was easily achieved by adding 30 mL of PBS and 15mL of methanol to the reservoir which had 15mL of methanol remaining after flushing the column. Of the 60 mL of the 50/50 methanol mix, 45 mL was pumped through the column (the equivalent of three times the volume of the column). After the 50/50 mix was pumped through the column, the next step was to return the fluid in the column to 100% PBS before adding the sample. This was achieved by adding PBS to the stirrer 15mL at a time six times while the peristaltic pump continued to pump through the column. The result of this step left the fluid in the column as <1% methanol, which we considered to be acceptably close to 100% PBS for our purposes.

While the column was being returned to 100% PBS the sample was prepared for injection into the column by pumping 10 mL of the dye into the sample loop selector valve using the sample burette pump. The volume of the loop is only 0.5 mL however a much larger volume was pushed through the loop to ensure that the sample loop contained only the sample. The sample loop is filled while the valve is in the "on" position. In the "on" position, fluid pumped by the sample burette flows through the sample loop and passes directly to the sample waste reservoir. Once the sample was pumped into the loop and the column was filled with 100% PBS, the loop valve was switched to the "off" position. This allowed the 5mL/min peristaltic pump to pump the elutant through the sample loop to push the sample in the loop into the column. The elutant at this point was changed to 10% methanol by adding methanol and PBS to the stirrer while the peristaltic pump was switched "off".

The next phase of the experimental program was the methanol gradient, which incrementally increased the concentration of methanol from the starting concentration of 10% to the final concentration of 75% over 40 minutes. To ensure the correct concentrations, the starting volume of 10% methanol was fixed at 40mL and that volume was maintained throughout by adding 5mL of a combination of PBS and methanol every minute to compensate for the amount being pumped every minute by the peristaltic pump.

After the completion of the methanol gradient the methanol concentration was increased to 100% by adding methanol to the stirrer 15mL at a time while continuing to run the peristaltic pump. This was repeated several times until the concentration of methanol was sufficiently high to ensure that all contaminants were flushed from the column and the fluid in the column was 100% methanol. At this point, the flows were turned off and the cap was placed over the exit of the column to store it until the next test.

Flow Path Description

The flow path of the various fluids through the instrument are shown in the following figure. The color code for each fluid is as follows: Green is used to show the flow path of the pure PBS, red is used to show the flow path of pure methanol, orange is used to show the flow path of the elutant which can be PBS, methanol or some combination of the two depending on the point in the chromatography program and black is the sample flow path of the sample when the sample loop valve is in the "on" position (the only difference in the "off" would be that the loop itself would be orange instead of black indicating that the elutant from the peristaltic pump is flowing through the loop). The blue arrows in the figure are

used to show the direction of the flow in each piece of tubing. It should be noted that any piece of tubing that is not one of the colors mentioned above is not used in this experiment.

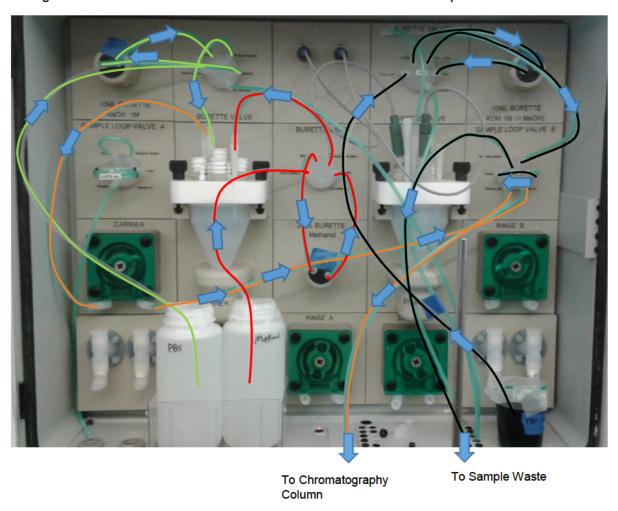


Figure 2. Instrument Flow Path Diagram

Chromatography

The initial sample was a combination of 5 food dyes dissolved in 1X PBS buffer at pH 7.3. The first test used a sample with small and varying concentrations of each dye. In the second test, each dye was .02% in 1X PBS by weight (See Table 1). We programmed the Applikon instrument to prepare the column with a variety of flushes, then load the mixed sample, and finally gradually increase the percent methanol in the elutant buffer for a completely automated process with no hands-on processing. Specifically, we used one burette pump with sample loop to inject a precise amount of sample to the column. We used the other two burette pumps and valves to add varying amounts of methanol or 1X PBS to the stirrer/supply vessel. The stirrer/supply vessel mixed the incoming volumes to produce a smooth steady gradient that was continuously pumped out through the peristaltic pump, and through the sample loop valve to the column. We collected the fractions off the column manually because we did not have an autosampler to collect them for us. The name of the routine that we programmed using the display and interface that was provided native to the Applikon instrument was called "chrom test2"

All components used came with the Applikon instrument as it was delivered to us. The device is designed to suit particular processes and applications and as received it was suited for higher flow rates than we needed. We purchased a different peristaltic pump from Applikon that was rated for smaller flows to make it more compatible with lab-scale chromatography systems. We also used new peristaltic tubing since we did not know the condition of the peristaltic tubing itself. To perform the chromatography, we used a common C18 chromatography column (Biotage part # FSL0-1118-0012), and an adapter (Idex Health& Science part # P-650) to connect the tubing from the Applikon instrument to the column. All food dyes were purchased from (Flinn Scientific part # AP7375).

The hands-off program clearly separated the 5 food dyes from each other with what appears to be a baseline separation between them. Test A was performed on 11-3-16 with a mixture containing only a small concentration of each of the food dyes, then in Test B (performed 11-4-16), the concentration of mixed food dyes was increased for better visibility in the photographs and also to show reproducibility. Test C (11-11-16) was a repeat of Test B, and was filmed from start to finish. In Test D (11-14-16), several physical components of the Applikon system were switched relative to the previous 3 tests. Specifically, the "sample loop valve B", and the "rinse B" peristaltic pump were switched and also the "carrier" peristaltic pump, and the "sample loop valve A" were switched in the instrument. After switching these components, and the same chromatography was performed a 4th time. Test D showed that two of the various subcomponents could be easily switched in about 10 minutes time, and the chromatography results after the switching were unaffected. The entire chromatography separation process was filmed for Test C. The switching of the "carrier" peristaltic pump, and the "sample loop valve A" and the immediate Test D that followed was also filmed.

In Tests A, B, C, and D the vials were numbered and collected at the same time so that the vial number would be directly comparable in each of the other tests. Because manual collection times were not identical for each collected tube (some were 50 seconds and others 60 etc.), some tubes ended up with more volume than can be capped without spilling. Capping was useful to photograph all the eluted dyes in a single image so some of the liquid from the tops of some tubes was poured or pipetted out to allow capping and subsequent photographing. Below is a summary of the results shown in Table 1 and Figures 3-6. The results are quite reproducible with each of the 5 colored peaks eluting at the same times in all four tests.

Table 1 Description of individual dyes present in the separated mixture and listing the vial and corresponding elution time for each dye present.

	Test A mixture	Test B mixture	Test C mixture	Test D mixture	Center	Center of peak
	(initial wt. %	(initial wt. %	(initial wt. %	(initial wt. %	of peak	elution time
	dye in 1X PBS)	(vial #)	(minutes)			
Yellow 5	0.0077	0.02	0.02	0.02	6-7	51.1
Yellow 6	0.0084	0.02	0.02	0.02	14-15	58.1
Red 40	0.0024	0.02	0.02	0.02	18-19	101.6
Blue 1	0.0038	0.02	0.02	0.02	24-25	107
Red 3	0.002	0.02	0.02	0.02	34-35	116.5

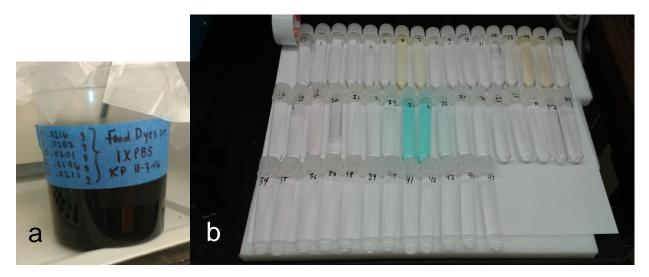


Figure 3. Test A at low dye concentration. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

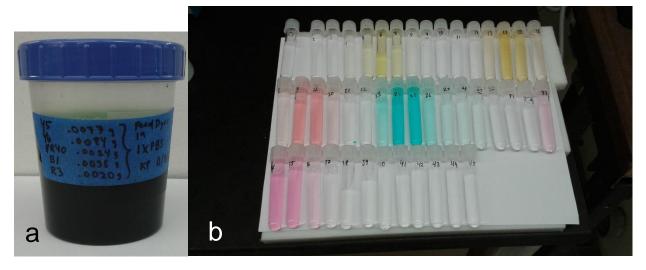


Figure 4. Test B at higher dye concentration. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

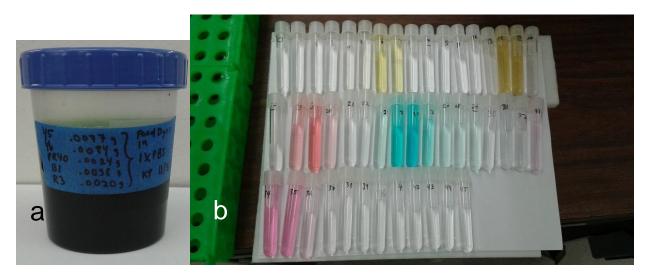


Figure 5. Test C at higher dye concentration. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

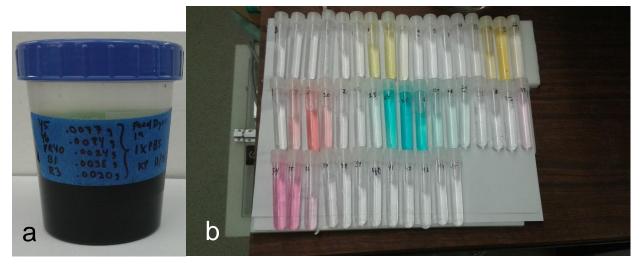


Figure 6. Test D at higher dye concentration and after switching instrument components. a) starting mixture of dyes. b) separated dye by fractions collected. The centers of each peak of eluted colors were at vials 6-7, 14-15, 18-19, 24-25, 34-35.

The colors of each individual dye as diluted in 1X PBS match the hues found in the fractions collected after chromatography. Each dye also elutes in the order expected based upon the results of others who have separated food dyes on C18 columns under similar conditions.



Figure 7. Individual dilutions of dry dye powders in 1X PBS from left to right: FDC Yellow #5, FDC Yellow #6, FDC Red #40, FDC Blue #1, FDC Red #3.



Figure 8. Fluidic components for chromatography. a) layout for the first three tests (Tests A, B, C). b) layout for the last test (Test D). Note the switched location of "carrier" peristaltic pump, and the "sample loop valve A". We also switched the location of "rinse B" peristaltic pump and "sample loop valve B" but this was not filmed.

EXHIBIT 5

FILED UNDER SEAL

Media Included

Exhibits Transcript

Word Index



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1
                IN THE UNITED STATES DISTRICT COURT
 2.
               FOR THE SOUTHERN DISTRICT OF NEW YORK
 3
 4
     GE HEALTHCARE BIO-SCIENCES AB, GE
     HEALTHCARE BIO-SCIENCES
 5
     CORPORATION, and GENERAL ELECTRIC
     COMPANY,
                                            Civil Action No.
 6
                  Plaintiffs,
                                            1:14-cv-07080-LTS-SN
 7
     vs.
 8
     BIO-RAD LABORATORIES, INC.,
 9
                  Defendant and
10
        Counterclaim Plaintiff.
11
12
13
14
              VIDEOTAPED DEPOSITION OF METROHM 30(b)(6)
                   (LARRY TUCKER and THOMAS KOSHY)
15
                           Tampa, Florida
                           August 10, 2015
16
17
18
19
20
21
22
     REPORTED BY:
     RHONDA HALL-BREUWET
23
     RDR, CRR, LCR, CCR, FPR, CLR
     NCRA Realtime Systems Administrator
24
     Job No.: 10018443
25
```

1	A. Yes.
2	Q. Is that an accurate statement?
3	A. Yes.
4	Q. So sitting here today, you don't have any
5	information about whether the ADI 2040 has been used
6	for liquid chromatography; is that right?
7	A. So yes, I have no records reflecting that
8	the 2045 VA or TI have been used for ion
9	chromatography in the U.S.
10	Q. Have you ever heard that the 2040 or 2045
11	was used for liquid chromatography?
12	A. No, I have not. I'm aware of I've heard
13	talk of projects where other process analytical
14	groups globally have sold units for ion
15	chromatography online, but I don't have the details
16	as to whether they specifically used the 2045 VA or
17	TI.
18	Q. I'm sorry. You said you've heard that units
19	were sold for ion chromatography?
20	A. That's correct. We have typically a yearly
21	meeting, and I had seen a presentation where someone
22	had sold a system for ion chromatography. I don't
23	recall if it was based on the 2045 VA or TI.
24	Q. And do you know what system that was?
25	A. I do not know. It may have been built on

1	MR. DAVIS: Objection. Form.
2	THE COURT REPORTER: I'm sorry. For what?
3	I didn't hear the end of your question.
4	MS. SKLENAR: I asked if he had ever seen
5	internally a 2040 or 2045 system used for liquid
6	chromatography applications.
7	MR. BILSKER: Objection. Compound.
8	MR. DAVIS: And I objected to the form.
9	MS. SKLENAR: I'll break it up.
10	BY MS. SKLENAR:
11	Q. Have you ever seen a 2040 be used for liquid
12	chromatography, within your company?
13	A. Not within the U.S., no, I haven't seen
14	that.
15	Q. Have you seen it be used anywhere for liquid
16	chromatography, the 2040?
17	A. I've seen no, not with the 2040.
18	Q. Have you seen the 2045 VA be used for liquid
19	chromatography?
20	MR. DAVIS: Same objection. You can answer.
21	THE WITNESS: No, I have not, not in the
22	U.S.
23	BY MS. SKLENAR:
24	Q. You say "not in the U.S." Have you seen it
25	be used anywhere, the 2045, for liquid

Metrohm 30(b)(6) Larry Tucker and Thomas Koshy

GE Healthcare vs. Bio-Rad

1	
1	CERTIFICATE OF OATH
2	
3	STATE OF FLORIDA
4	COUNTY OF HILLSBOROUGH
5	
6	I, the undersigned authority, certify that
7	METROHM 30(b)(6) personally appeared before me and
8	was duly sworn.
9	
10	WITNESS my hand and official seal this
11	14th day of August, 2015.
12	
13	
14	Chlen, Dall Knewer
15	Rhonda Hall-Breuwet, RDR, CRR, LCR, CCR, FPR, CLR NCRA Realtime Systems Administrator
16	Notary Public - State of Florida My Commission Expires: 9/28/15
17	Commission No. EE 117263
18	
19	
20	
21	
22	
23	
24	
25	

```
1
                     REPORTER'S CERTIFICATE
     STATE OF FLORIDA
 2.
 3
     COUNTY OF HILLSBOROUGH
 4
 5
              I, Rhonda Hall-Breuwet, RDR, CRR, LCR, FPR,
 6
     CLR, NCRA Realtime Systems Administrator, Notary
 7
     Public, certify that I was authorized to and did
     stenographically report the deposition of METROHM
 8
 9
     30(b)(6); that a review of the transcript was
10
     requested; and that the transcript is a true and
11
     complete record of my stenographic notes.
12
              I further certify that I am not a relative,
13
     employee, attorney, or counsel of any of the parties,
14
    nor am I a relative or employee of any of the
    parties' attorney or counsel connected with the
15
16
     action, nor am I financially interested in the
17
     action.
18
              Dated this 14th day of August, 2015.
19
20
                      len. Dall Brewer
21
         Rhonda Hall-Breuwet, RDR, CRR, LCR, CCR, FPR, CLR
22
         NCRA Realtime Systems Administrator
23
24
25
```

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB, and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC,

Plaintiffs

C.A. No. 18-1899-CFC

Consolidated

v.

DEMAND FOR JURY TRIAL

BIO-RAD LABORATORIES, INC.,

HIGHLY CONFIDENTIAL

Defendant.

 $({\bf TECHNICAL})-{\bf ATTORNEYS'}~{\bf EYES}$

ONLY

REPLY EXPERT REPORT OF DR. BRUCE GALE

controlled fluid flow to a column, that separates components in a liquid, as I showed in my experiments.

- 35. Next, Dr. Wereley claims the court rejected the definition of a liquid chromatography system that I have been using. He provides no citation for that claim. I can address it if he does.
- 36. In any event, as I described in the prior paragraphs and in my opening report, the 2040 System does have detectors of the same type as mentioned in the asserted patents. Nor is it of any moment that some of the detectors in the 2040 System require calibration as Dr. Wereley claims is a basis for distinguishing the 2040 System. Wereley ¶ 325. There is no description in the asserted patents for how the detectors must function and certainly nothing that excludes something from being a detector simply because it must be calibrated. I understand that it is improper to read limitations into the claims from the specification and that it is even more improper to create limitations that are not even mentioned in the specification and import those into the claims. Thus, the need to calibrate a sensor does not disqualify it from being a detector under the asserted patents. If it does, detectors in the Bio-Rad accused systems would have to be disqualified. I confirmed with Ms. Schaefer, one of the Bio-Rad specialists in the NGC, that

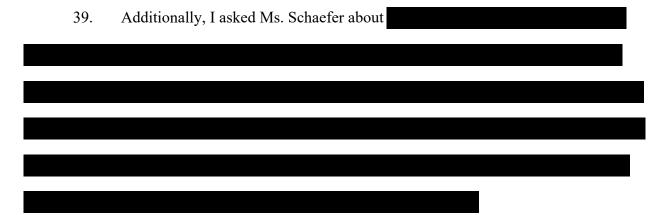
 The same is true of the AKTA systems. See e.g., GEHCDEL123052 at GEHCDEL123222 ("If pH will be measured during the chromatographic run, the pH monitor should be calibrated before the run is started.").

37. Next, Dr. Wereley claims that the 2040 System is not an automated liquid chromatography system because before running chromatography on the instrument, a significant amount of advanced planning went into the run like calculating salt and buffer concentrations, identifying a starch that would absorb the dyes and determining the concentration of methanol.

Wereley at ¶¶ 333, 339. It is difficult to understand Dr. Wereley's argument. The fact that calculations had to be done before performing the chromatography to determine what buffers to use, what kind of column to use and what liquid constituents to use to illustrate the separation that the 2040 System liquid chromatography system would perform does not mean it is not a liquid chromatography system. It simply means that the parameters of that particular separation had to be determined. I do not consider the time spent on the calculations to be anything out of the ordinary. In fact, the system was able to perform liquid chromatography quite easily. Dr. Wereley fails to consider that when workers buy machines now, they usually have field service representatives who have used the particular machines hundreds if not thousands of times come on site to teach the user how to use the machine. That did not happen here. Rather, we were able to figure out how to use the machine relatively easily simply from reading the manual. Moreover, many if not all of the same type of calculations would have to be performed even if using the Bio-Rad or Cytiva machines. I confirmed this with one of Bio-Rad's field specialists, Katie Schaefer. Ms. Schaefer told me that she had experience as a graduate student using the Akta machines as well as extensive experience using the NGC. Mr. Schaefer confirmed what I understood, and what is known by anyone of ordinary skill who actually performs chromatography on an instrument, that the first time you run a particular LC separation experiment, you will have to do the types of calculations we did to determine buffers, concentrations flow rates, column material etc. That is as true for the Plaintiffs' Atka machines and, Bio-Rad's accused machines as it is for the 2040 System prior art system.

38. If Dr. Wereley actually believes that one could approach a Plaintiff or accused machine the first time running an experiment and somehow type in what you wanted to do and then hit a button and have the machine run, he is clearly mistaken. On the Bio-Rad machine, for

example, the only information that is calculated on its own relates to the columns. If you identify a column for use which happens to have been preloaded on the instrument, it will recognize the volume and the maximum pressure. It can then insure that instrument is not set for example to exceed the maximum pressure. But that is a far cry from what Dr. Wereley seems to be saying.



- 40. Given those metrics, I believe we spent much less time getting the 2040 System machine to perform chromatography. We had no one come in to help us learn how the system operated. All we had was the user manual. Moreover, as I said, the user interface on the 2040 System was not as easy to use as more modern interfaces. That slowed us down a little as well. Nonetheless, we were able to get the 2040 System to perform a chromatography experiment in an amount of time and with an amount of work that was less than or at least in the same range as a user who purchases an accused Bio-Rad device
- 41. Moreover, to the extent that Dr. Wereley is claiming that some never used before programming had to be done to modify the 2040 System machine to perform chromatography, that is not the case and it is a distortion of the process. The "programming" that Dr. Wereley refers to in paragraphs 340-349 of his rebuttal report is merely selecting from the menu driving system how long and in what order certain components of the system would operate. Those are

values that are available on the system and that the user manual teaches you how to select.

Nothing was added to the machine to do this. We just used the existing information available on the machine. This is no different than planning that has to be done on the Bio-Rad or Cytiva machines, which both require that the user create a method before performing a liquid chromatography experiment. See, e.g., BRGEDEL000000497 at BRGEDEL000000703-58 ("Creating a method" section of NGC user guide); GEHCDEL123052 at GEHCDEL123153-67 ("Create a method" section of AKTA avant user manual). Dr. Wereley's characterization of the tests and "programming" are not presented in an accurate manner at all. As I said, the machine was not modified and nothing out of the ordinary was done in using the machine. The fact that the user interface from a machine created in the late 1990's may not have been as easy to use as one created 15 or 20 years later does not mean the earlier machine, in this instance the 2040 System, is not an automated liquid chromatography instrument.

42. Dr. Wereley's claim that the "programming" of the 2040 System to perform liquid chromatography is akin to programming a series of complicated steps for a VCR player that are not described in the system manual is not correct at all. Wereley ¶ 344. Nor is his claim that he has been denied access to programming that was done. The values selected to run on the machine were all saved in a file that was viewable on the 2040 System and that he and his lawyers viewed and appear to have taken pictures of. Those files were also produced to Dr. Wereley. BRGEDEL000610738 - BRGEDEL000610745. The fact that the files could not be easily copied onto a disk or printed is simply a function of the machine being old and me not having access to all the equipment to do such a download when I was asked after the fact during Covid to do so. I note that neither Dr. Wereley nor his lawyers provided me with any of the old devices for such downloads though they have known about the 2040 System machine, and had

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the extensive user manual describing how such downloads could be done for more than a year. This whole discussion of lack of access seems to be a diversion to take attention off the real issue: the 2040 System machine easily performed liquid chromatography and was readily programmed to do so.

43. Moreover, the claim that the complicated series of steps were put into the machine that were nowhere described in the manual is clearly not true again. The steps that were performed were very much described in the manual and that is how we learned to do them. For example, there is extensive description for how to use the burette modules and how to set their parameters to sample and dose. For example, the whole Configuration Part of the Manual, (BRGE 3407-3450) which is like a detailed book chapter with six separate sections, describes how to configure the various modules and sensors. See, e.g. BRGE 3312-3315, 3443-48 (configuring burette modules). It also describes the input methodology of the user interface which used a single key to represent multiple letters like a phone keypad. The Advanced Operation Part is another detailed chapter with multiple sections (BRGE 3453-3532). For example, at pages 3472-74 there is a description for how to select parameters for the burette modules, how to have the sample detected during a run (BRGE 3476), how to take actions during a run based on calculations (BRGE 3477-3486), how to add software programs (BRGE 3518) and errors that might occur during a run (BRGE 3521-3528) like some of the time programs may not be compatible with each other. The Basic Operation chapter details many of the same things, including alarms that sense various parameters during a run and take certain actions in response. BRGE 3553-55(showing graph of pH measurements). There are other chapters that provide extensive details for other operations, like the Serial Communication

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DATED: November 11, 2020	Jan & Ade
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EXHIBIT 7

FILED UNDER SEAL

11/18/2020

Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.

Kevin Petersen

Page 1	Page 3
UNITED STATES DISTRICT COURT	¹ APPEARANCES
FOR THE DISTRICT OF DELAWARE	² (Via Zoom Videoconferencing):
Cytiva Sweden AB et al.,	4 ON BEHALF OF PLAINTIFF Cytiva Sweden AB et al.:
Plaintiff,	MICHAEL J. SEBBA, ESQUIRE 5 ARNOLD & PORTER KAYE SCHOLER LLP
Civil Action	5 ARNOLD & PORTER KAYE SCHOLER LLP 250 West 55th Street
-against- No. 18-1899-CFC	6 New York, New York 10019-9710
Bio-Rad Laboratories, Inc.,	PHONE: 212.836.7529
Dio rad Edoordiories, inc.,	F-MAIL: Michael.sebba@arnoldporter.com
Defendant.	8
	9 ON BEHALF OF DEFENDANT Bio-Rad Laboratories, Inc. and
VIDEO-RECORDED DEPOSITION OF	the witness
KEVIN PETERSEN	DAIVD BILSKER, ESQUIRE
Zoom Recorded Videoconference	QUINN EMANUEL URQUHART & SULLIVAN LLP 50 California Street
11/18/2020	22nd Floor
1:37 p.m. (CST)	San Francisco, California 94111
	PHONE: 415.875.6600
	E-MAIL: Davidbilsker@quinnemanuel.com
	14
REPORTED BY: AMANDA GORRONO, CLR CLR NO. 052005-01	15 ALSO PRESENT:
CLR NO. 032003-01	16 Sean Damon, Esquire, Quinn Emanuel Urquhart & 17 Sullivan I I P
	 Sullivan LLP Andy Mortensen, Legal Videographer, Digital Evidence
	19 Group
DIGITAL EVIDENCE GROUP	20
1730 M Street, NW, Suite 812 Washington, D.C. 20036	21
(202) 232-0646	22
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1 11/18/2020	1 INDEX
2 1:37 p.m. (CST)	² WITNESS EXAMINATION BY PAGE
3	³ KEVIN PETERSEN MR. SEBBA 7
4 VIDEO-RECORDED DEPOSITION OF KEVIN PETERSEN,	4 MR. BILSKER 151
5 held virtually via Zoom Videoconferencing, before	5 MR. SEBBA 168
note virtually via zoom videocomorenemy, cerete	6 MR. BILSKER 170
6 Amanda Gorrono, Certified Live Note Reporter, and	7
Notary Public of the State of New York.	8 EXHIBITS
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10	Exhibit 291 Kevin Petersen's LinkedIn
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19 20	Report
	20 Exhibit 299 Screengrab 1 123
20	

11/18/2020 Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. Kevin Petersen Page 45 Page 47 1 get the device, you know, physically in the location problems we're having. 2 (inaudible) power supply figured out. And let's see, later he -- I think we 3 3 I think that, you know, the actual -came to him at one point and said we were able to get 4 4 during the bulk of the testing happened in probably to do chromatography, and here's some of our data. 5 5 about a 39-hour time frame. It probably took -- at He's like great, the lawyers would like you to film 6 6 least in my time. I don't know Travis's time, but it it now. So okay. So I think we filmed it at some 7 was probably about -- about 40 hours worth of work. point and said okay, now the lawyers would like you 8 8 to switch components. So okay, so we moved this to With the actual -- once you figured out what the 9 system is actually doing, and you just want to try 9 there and that to there. And so we filmed that we 10 10 and run some tests. So it was not a lot. could switch it too. 11 11 So when you say -- when you're That's -- as far as I remember, 12 12 estimating that 40 hours, what steps were done in that's mostly what -- I think I asked him later, you 13 13 those 40 hours? know, should I go this direction or that direction? 14 14 Again, this is where I have to He said he didn't think those issues were necessary 15 15 compare what my notebook says relative to when I just yet, or at all. Mostly we just waited for him 16 16 submitted times to Dr. Gale. So I would suspect that for general directions as to what he wanted us to do, 17 17 steps that were probably done in that were, one, and we were able to do it. 18 18 figuring out how to do the gradients, how to actually And you weren't given direction by 19 19 pump it, verify that it does pump it, get the anyone else? 2.0 20 programming all done, and actually have it do A. No. 21 21 So is if fair to say that the only chromatography and see if it separated anything. O. 2.2 So the bulk of the steps were 22 people involved in the Applikon Project were -- would Page 46 Page 48 1 1 probably done in -- at least in the terms of the time be you, Mr. White, and Dr. Gale? 2 I spent. I don't know about Travis's hours. 2 A. Yes. 3 3 Q. Were you provided any documents with Q. Okay. Did you read the entire 4 4 the 2040 System? hardcopy 2040 manual that you mentioned before? 5 5 A. So, I looked for the manuals, because A. No, certainly not. 6 6 I thought sure we had a manual. But I didn't see any Q. Do you know what parts of it you 7 7 electronic copies of manuals in the documents I read? 8 8 provided, so I must have been given a hardcopy We would have read the parts related 9 9 manual. So either Travis or I would have followed to programming it, we would have read parts related 10 10 to hardware-specific questions we may have had. I -the hardcopy manual, or even Travis may have hardcopy 11 11 manual. Travis may have found an electronic manual, I don't remember. Again, this is four years ago 12 since I've even, you know, seen this. 12 but I believe we worked off of a hardcopy manual that 13 1.3 came with the instrument. Did you find any sections of the 14 14 manual that specifically discuss liquid Were there any other documents that 15 1.5 chromatography? you operated off of? 16 16

Again, I don't remember that one

manual for using the 2040 System to perform ion

It's been too long since I've

question. I don't know.

chromatography?

actually had a manual in front of me to answer that

Did you find any instructions in the

A. No.

Applikon Project?

So what was Dr. Gale's role in the

chromatography. We would give him occasional updates

A. So, he -- he came to us, like I

and say this is where we're at, these are the

mentioned, and said we'd like you to make this do

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11/18/2020

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spreadsheets.

O.

to Mr. White's notes?

Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.

Kevin Petersen Page 91 1 requesting factual information from a fact witness is 2 well beyond the fact discovery period. 3 THE TECH: Mr. Bilsker, do you know 4 how to dial in on your phone? 5 MR. SEBBA: If this is going to take 6 time, let's go off the record. 7 THE TECH: It may take a couple 8 minutes. 9 MR. SEBBA: Well, we're not -- if 10 you're putting an artificial deadline on this, we're 11 not going to waste time with your technical --12 technological issues on the record. 13 MR. BILSKER: I'm using the system 14 that you've set up. I've never had a problem before. 15 The court reporter for some reason says she can't 16 hear me, that's not my problem. 17 MR. SEBBA: It's your microphone on 18 your -- on your system. That's the issue, because 19 everyone else is fine. 2.0 MR. BILSKER: I object. I object. 21 Your Document is not proper. 22 MR. SEBBA: All right. Let's Page 92 1 continue. 2 BY MR. SEBBA: 3

Page 90

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22

1 I don't know what happened to those, other than 2 perhaps I discarded them.

So the -- the notes that, like I

mentioned, you know, Travis would have kept notes on

more of the detailed questions on how the programming

In terms of, you know, what he and I

did together, you know, we, of course, figured out

how to make the gradient occur, and those notes are

reflected there and they're written down. And then

they -- they're in a spreadsheet that was provided,

calculations were done. So these were done in

Do you know if Mr. White --

Do you know what would have happened

So according to an E-mail that I saw

from Dr. Gale, Travis left them in my lab or in my --

in my -- what's it called -- my -- my lab area. And

when I moved to Rochester, I think I discarded it.

notebooks, I don't have a copy of it. Unfortunately,

But I have looked everywhere, it's -- among my

MR. SEBBA: Withdrawn.

as well, that shows how that -- how those

- Do you know how Dr. Gale knows that Mr. White left the lab notebook in your lab area?
- 5 When Dr. Gale, he forwarded the 6 E-mail from Travis to me. And I saw it, he said, see 7 Travis' reply below, so...
 - When did he forward you that --MR. SEBBA: Withdrawn.
- 1.0 When did Dr. Gale forward you that 11
- E-mail from Mr. White? 12 A.
 - I don't remember. Within the last two weeks anyway.
- 14 Did you provide that E-mail that 15 Dr. Gale forwarded to Mr. Bilsker and Mr. Damon?
 - A. Yes, I did.
 - Okay.
- 1.8 MR. SEBBA: David, we're going to 19
- request that document. 20 (Whereupon, a request for Document,
- 21 was made.) 22
 - MR. BILSKER: As I have said before,

- Dr. Petersen, would there have been other documents that were -- that were used in planning the development of the program chrom test on this 2040 System?
 - No. Other than what I've mentioned, no.
 - Was this program run on the 2040 --MR. SEBBA: Withdrawn.
- Q. Was the program chrom test run on the 2040 System?
- 13 I would assume all of the ones that I 14 actually wrote are -- are -- were run on the system 15 at some point.
 - Q. Who would have run them?
 - A. Either Travis or myself.
- 18 And what was the result of running Q. 19 chrom test?
 - I don't remember what was the result of running chrom test itself. When you're developing a program, you always go through various

23 (Pages 89 to 92)

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Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.

Kevin Petersen

Page 97 Page 99 1 1 THE TECH: (Complying.) The manual I'm sure Travis would have A. 2 2 O. All right. Let's focus on the used. 3 3 program titled chrom test2. So you believe that you Q. Were there any notes referred to 4 4 and Travis White created the program chrom test2, during the programming of chrom test2? 5 5 A. Again, it would have been in Travis's correct? 6 6 A. Yes. notebook. 7 O. Would that program have been entered Q. Okay. Were there any flow charts 8 8 through the interface shown in this photo of the created when programming chrom test2? 9 9 No. Not that I'm aware. 2040 System? A. 10 10 A. O. And so was chrom test --11 11 O. Who would have entered it? MR. SEBBA: Withdrawn. 12 12 Travis primarily, and then I would Was the program chrom test2 run as A. Q. have also entered things as well. 13 13 part of the Applikon Project? 14 14 Who would have been present while you A. Yes. 15 15 and Travis were entering all the steps in this Q. By whom? 16 16 By myself and by Travis. program? A. 17 17 A. Q. And what were the results? Just Travis or I. 18 18 Q. And how long would that have taken? A. That we were able to put a dye into a 19 19 I don't remember, unfortunately. It chromatography column automatically hands off, and 20 20 didn't seem like it took too long, but it was a very then change the gradient across that chromatography 21 21 bold interface, and so it wasn't as easy as just column, and then dilute the individual dyes in almost 22 22 a baseline fashion. In other words, it worked very typing in a value. You had to literally go through Page 98 Page 100 1 1 and add each one. well. It was also very reproducible. Every time we 2 2 Q. Do you have an estimate on how long run that it gave very reproducible values in terms of 3 3 it took? the times the dyes came off, and just the order of 4 4 A. I -- unfortunately, I'm not the best things like that. It was very reproducible. 5 5 How many times did you run that person to ask on the estimate of time, simply because Q. 6 6 it's so long ago. But it does -- it was not -- it experiment? 7 7 didn't seem like it took an unreasonable amount of A. I think two or three. I'd have to 8 8 time. look at the final report. 9 9 Would have that been recorded in the Do you remember when you first were 10 1.0 timesheet that you provided to Mr. Bilsker and able to run that experiment? 11 11 Mr. Damon? A. Not exactly. And when you say "that 12 12 A. The time that it spent to physically experiment," you remember there's a -- there's an 13 13 stand up the instrument and program in the inputs? iterative process, right? Where you run it and say, 14 14 Is that the question? do I need to change the program at all? If it works, 15 15 Q. Yes. then you say, okay, that's good, and you don't touch 16 16 A. No. It wouldn't be reflected there. the program anymore. 17 17 Okay. How many inputs were required Approximately how many iterations of 18 18 to create the program chrom test2? this program did you create in the Applikon Project? 19 19 I don't remember. But the program is A. I don't know. If you were to look at 20 20 on the instrument, so you can see for yourself. the actual panel and say, oh, all of those are 21 21 different programs and how many iterations were Were there any documents used as a 22 22 reference during the programming of chrom test2? there? It depends on what you call an iteration.

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Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.

Kevin Petersen

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Page 173
                                                                                                                          Page 175
        reliance on Dr. Petersen's work.
                                                                        1
                                                                               CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC
                                                                        2
                                                                                     I Amanda Gorrono the officer before
 2
                 THE WITNESS: What is Exhibit 4? Can
                                                                              whom the foregoing deposition was taken, do hereby
 3
        you remind -- can you remind me what that one is?
                                                                              certify that the foregoing transcript is a true and
                 MR. SEBBA: That's your lab report.
                                                                              correct record of the testimony given; that said
 5
                 THE WITNESS: Oh, okay. So it was --
                                                                              testimony was taken by me stenographically and
 6
        I -- I want to clarify your statement, Mr. Sebba. I
                                                                              thereafter reduced to typewriting under my direction;
        didn't necessarily draft it. It's definitely a joint
                                                                              and that I am neither counsel for, related to, nor
                                                                              employed by any of the parties to this case and have
 8
        report with Travis and myself, you know. It -- it
                                                                              no interest, financial or otherwise, in its outcome.
        may have been that Travis -- in fact, probably Travis
                                                                                     IN WITNESS WHEREOF, I have hereunto
10
        typed up the initial draft and I edited it from
                                                                              set my hand this 18th day of November, 2020.
11
        there.
12
                 MR. SEBBA: Understood. Thank you
                                                                       10
                                                                       11
13
        for the clarification.
                                                                       12
14
                 MR. BILSKER: And just to respond to
                                                                       13
15
        you, Mr. Sebba. I don't think that changes anything.
                                                                       14
16
        It doesn't move the needle. You don't understand the
                                                                       15
                                                                              AMANDA GORRONO, CLR
17
        Federal Rule of Civil Procedure 26.
                                                                              CLR NO: 052005 - 01
18
                                                                       17
                  The language of Federal Rule of Civil
                                                                       18
                                                                              Notary Public in and for the State of New York
19
        Procedure 26 clearly says, someone who you are going
                                                                       19
                                                                              County of Suffolk
2.0
        to rely on. Dr. Gale relied on his -- on
                                                                       20
                                                                              My Commission No. 01G06041701
21
        Dr. Petersen's report and the data, so there's
                                                                       21
                                                                              Expires: 01/07/2023
22
        nothing improper about anything that we did.
                                                                       22
                                                  Page 174
                                                                                                                          Page 176
                                                                        1
                 Anyway, Dr. Petersen, thank you very
 1
                                                                                 Kevin Petersen, c/o
                                                                                 QUINN EMANUEL URQUHART & SULLIVAN LLP
 2
        much for your time. Sorry that you had to be
                                                                                 50 California Street, 22nd Floor
 3
        inconvenienced. I'll let you get back to your family
                                                                                 San Francisco, California 94111
 4
        and dealing with all of those things that we have to
 5
        deal with right now with COVID.
                                                                                Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
                                                                                 Date of deposition: November 18, 2020
                 MR. SEBBA: Thank you for your time,
                                                                        5
                                                                                 Deponent: Kevin Petersen
 7
        Dr. Petersen. We appreciate it.
 8
                 THE WITNESS: Oh, thank you to
                                                                                Please be advised that the transcript in the above
 9
        everyone who's involved in this process. Thank you.
                                                                                referenced matter is now complete and ready for signature.
10
                                                                                The deponent may come to this office to sign the transcript,
        I learned a lot, and it's -- it's been a fun
                                                                       10
                                                                                a copy may be purchased for the witness to review and sign,
11
        experience. And good luck to both of you in your
                                                                       11
                                                                                or the deponent and/or counsel may waive the option of
12
        prospective works. So thank you.
                                                                       12
                                                                                 signing. Please advise us of the option selected.
13
                 MR. SEBBA: Thanks.
                                                                       13
                                                                                Please forward the errata sheet and the original signed
14
                                                                       14
                 MR. BILSKER: Yeah. We can go off
                                                                                 signature page to counsel noticing the deposition, noting the
                                                                       15
                                                                                 applicable time period allowed for such by the governing
15
        the record, but, Kevin, I do have a question for you.
                                                                       16
                                                                                 Rules of Procedure. If you have any questions, please do
16
                 THE VIDEOGRAPHER: Okay. Is there
                                                                       17
                                                                                not hesitate to call our office at (202)-232-0646.
17
        anything else we need to get on the record?
                                                                       18
18
                 MR. SEBBA: Nothing else.
                                                                       19
                                                                       20
19
                                                                                 Sincerely,
                 THE VIDEOGRAPHER: Okay. The time is
                                                                                 Digital Evidence Group
20
        5:07 p.m., and this concludes today's video
                                                                       21
                                                                                 Copyright 2020 Digital Evidence Group
21
        deposition of Kevin Petersen.
                                                                                Copying is forbidden, including electronically, absent
22
                 (Time Noted: 5:07 p.m. (CST)
                                                                       22
                                                                                express written consent.
```

11/18/2020

Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.

Kevin Petersen

	Page 177
1	Digital Evidence Group, L.L.C.
2	1730 M Street, NW, Suite 812
۷.	Washington, D.C. 20036 (202) 232-0646
3	
4	SIGNATURE PAGE
5	Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. Witness Name: Kevin Petersen Deposition Date: November 18, 2020
6	1
7	I do hereby acknowledge that I have read and examined the foregoing pages
8 9	of the transcript of my deposition and that:
10	(Check appropriate box):
	() The same is a true, correct and
11	complete transcription of the answers given by
12	me to the questions therein recorded. () Except for the changes noted in the
	attached Errata Sheet, the same is a true,
13	correct and complete transcription of the
14	answers given by me to the questions therein recorded.
15	
16 17	DATE WITNESS SIGNATURE
18	DAIL WITNESS SIGNATURE
19	
20 21	
22	DATE NOTARY
	Page 178
1	Page 178 Digital Evidence Group, LLC
1 2	
	Digital Evidence Group, LLC
2	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812
2	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036
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2 3 4 5	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036
2 3 4 5 6 7	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036 (202)232-0646 ERRATA SHEET
2 3 4 5 6 7	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036 (202)232-0646 ERRATA SHEET Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
2 3 4 5 6 7 8	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036 (202)232-0646 ERRATA SHEET Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. Witness Name: Kevin Petersen
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036 (202)232-0646 ERRATA SHEET Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. Witness Name: Kevin Petersen Deposition Date: November 18, 2020
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Digital Evidence Group, LLC 1730 M Street, NW, Suite 812 Washington, D.C. 20036 (202)232-0646 ERRATA SHEET Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. Witness Name: Kevin Petersen Deposition Date: November 18, 2020

EXHIBIT 8

FILED UNDER SEAL

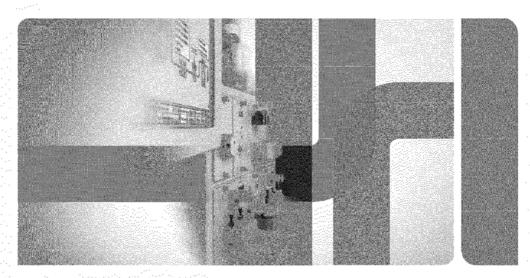
Case 1:18-cv-01899-CFC-SRF Document 194 Filed 12/22/20 Page 151 of 177 PageID #: 8055 Case 1:18-cv-01899-CFC-SRF Document 194 Filed 12/22/20 Page 152 of 177 PageID #: 8056

EXHIBIT 9

FILED UNDER SEAL

ase 1:18-cv-01899-CFC-SRF Document 194 Filed 12/22/20 Page 154 of 177 PageID 8058

Chromatography



NGC Chromatography Systems

Comprehensive Solutions for Protein Purification



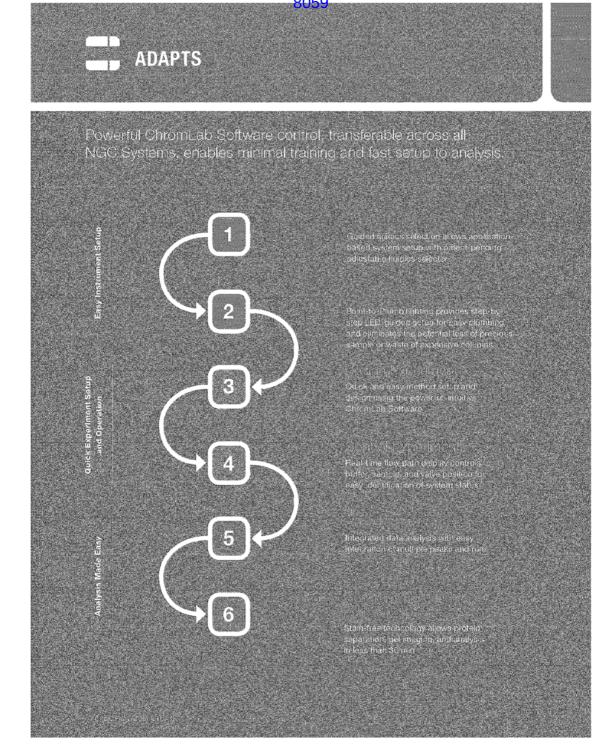


EXHIBIT 10 FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CYTIVA SWEDEN AB and GLOBAL LIFE SCIENCES SOLUTIONS USA LLC

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC., Defendant.

Civil Action No. 18-1899-CFC Consolidated

EXPERT REPORT OF PROFESSOR JAMES R. KEARL

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY

Bio-Rad Expert Report of J.R. Kearl

Bio-Rad Expert Report of J.R. Kearl October 21, 2020

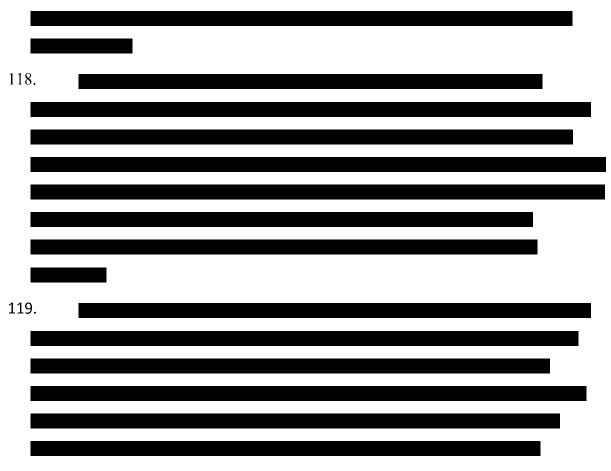
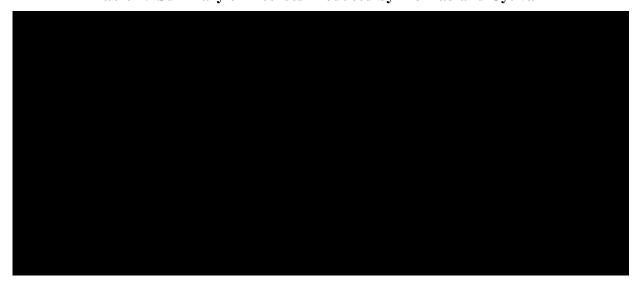


Table 4: Summary of Licenses Produced by Bio-Rad and Cytiva¹⁴⁸



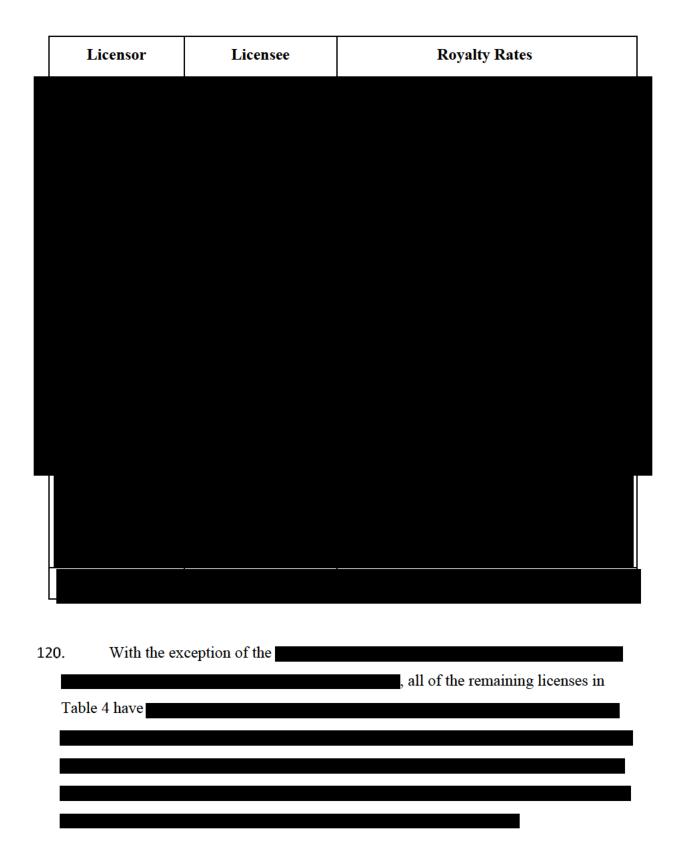
¹⁴⁸ See Exhibit F for more details

Case 1:18-cv-01899-CFC-SRF Document 194 Filed 12/22/20 Page 159 of 177 PageID #: 8063

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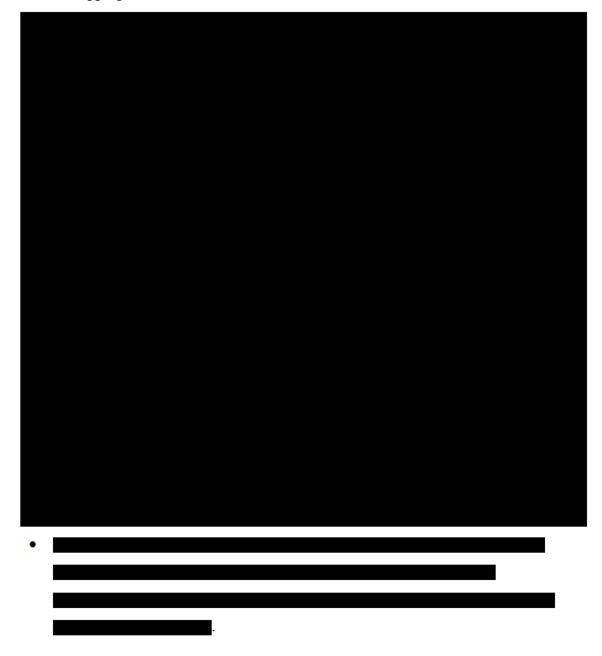
Bio-Rad Expert Report of J.R. Kearl October 21, 2020



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121. With regard to the license in Table 4, Mr. Bone does present some, limited, summary information that I provide here with some additional information from the licenses, as appropriate, for context.¹⁴⁹



¹⁴⁹ Bone Report, pp. 99-101.

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Mr. Bone's summary of his review of the licensed technologies suggests that they generally address function (the actual science being performed) rather than form (the design of the box within which the science is done). Although both function and form matter and the market success of Cytiva and Bio-Rad devices have demonstrated with their respective AKTA and NGC systems that ease of use improvements has value, more value is attributable to the function of the systems. However, Mr. Bone's per-unit dollar royalty implies that the modularity and flexibility he purports to have valued is at least than licenses the parties have entered into that address function.

By contrast, Mr. Bone's implied percentage royalty rates are in some cases near 14% for the low-end NGC Quest. To support implied royalty rates that are of this magnitude, Mr. Bone has to be implicitly assuming that the "flexible modularity" enabled by the in-suit patents is substantially more valuable than any of the technologies covered by the licenses in Table 4. Neither Mr. Bone nor I is qualified to determine the relative value of the particular in-suit technologies, but Mr. Bone cites to no evidence suggesting that the in-suit technologies are among the most valuable aspects of the devices ¹⁵². And, as I noted above, the value of these devices is primarily in their ability to do a particular kind of chromatography not in the form of the devices.

GP #3: The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.

124.	I assume that the hypothetical negotiation between GE and Bio-Rad would have
been fo	or a non-exclusive, worldwide license

¹⁵⁰ See Bone Report, para 173.

¹⁵¹ See Gale Rebuttal Report Section IV.

¹⁵² See Gale Rebuttal Report Section IV.

GP #4: The licensor's established policy and marketing program to maintain his
patent monopoly by not licensing others to use the invention or by granting
licenses under special conditions designed to preserve that monopoly.

- 125. The parties are competitors in the space for customers wishing to purchase medium pressure liquid chromatography equipment and, as such, Cytiva would be reluctant to license a technology that might give it market power. Further, Mr. Sorby testified that he is unaware of any Cytiva inquiries into licensing the patents-in-suit and that Cytiva has not attempted to license the patents-in-suit. If the technology indeed grants market power, a fact that Mr. Bone has not demonstrated, then Cytiva would seek a royalty rate that would compensate any loss of market power due to licensing a competitor.
- 126. In this instance, the Book of Wisdom suggests that the patents-in-suit do not push customers toward a single medium-pressure liquid chromatography supplier. Cytiva's overall market share is between 50-60% and Bio-Rad's is in the 6% range worldwide. Moreover, GE was the largest player in this field before the patents-in-suit and there is no quantitative evidence that suggests that its market share increased after embodying the technology in its current AKTA line. There is also no evidence that Cytiva's market share decreased with Bio-Rad's launch of its NGC line. Hence, Cytiva's market power due to the in-suit patents, if any, is limited and would not push the royalty rate up in a hypothetical negotiation.

154

¹⁵³ Sorby Deposition, p. 47:16-22.

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Bio-Rad Expert Report of J.R. Kearl October 21, 2020

GP #10: The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

The patents-in-suit are practiced in certain AKTA systems and the design of these

	systems allow for the customization of the instruments with alternative modules that can
	be swapped in and out with relative ease as customers' needs change.
	By entering into a license with Cytiva, Bio-Rad
	would avoid the cost of implementing the design around options it had available to it.
136	6. But since the value to consumers of the functionality enabled by the patents-in-
	suit is based on actual consumer purchases, the hypothetical negotiation would result in a
	modest royalty rate. Since my proposed upper bound of falls well within the range
	of actual licensed technologies, there is no reason to expect that it would be outside this

GP #11: The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.

range. ¹⁷⁰ There is certainly no support for Mr. Bone's implied royalty rates of up to 14%

137. Bio-Rad upgraded its chromatography instrument portfolio with the development of its NGC systems. Assuming infringement of the patents-in-suit, Bio-Rad has made use of the patented technology and Mr. Bone has estimated the total revenue of these

or his overall average implied royalty rate of 8.6%. 171

135.

¹⁶⁸ Wereley Report at para 62. Conversation with Phillip Chapman on October 14th, 2020.

¹⁶⁹ See Bone Exhibits 12.1-12.16.

¹⁷⁰ See Table 4.

¹⁷¹ See Exhibit B; Para 101.

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Bio-Rad Expert Report of J.R. Kearl October 21, 2020

systems to be and estimated gross profits of over a nearly six-year period, with an additional in revenue and in estimated gross profits of modules. However, more than of accused instrument revenues and profits derive from Bio-Rad's entry-level Quest system which Mr. Bone has not demonstrated would be in full, or in-part, captured by Cytiva. Further, since Mr. Bone has not determined an appropriate apportionment to the incremental modularity or customer use of that modularity, the value of the patents-in-suit on the NGC revenues and profits have not been shown to be an important the driving factor that would warrant a high royalty rate.

GP #12: The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

138.	The licenses provided in this matter covering different functional and form
tech	nologies, show that the portion of the selling price that is captured by a royalty to be
betw	ween with the majority being in the range. 174 Importantly, none
of th	ne licenses have royalties close to Mr. Bone's implied high rate of 14% or mean of
near	ly 9%, including licenses for technologies that are functional and not just form
relat	ed. ¹⁷⁵

¹⁷² Bone Tables 10, 11.

¹⁷³ See Bone Table 10. \$21,188,365/\$22,363,588 = 95%.

¹⁷⁴ Table 4.

¹⁷⁵ See Exhibit B; Para 93

GP #13: The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

- implies that most of the value of the devices the two parties sell is due to their use by purchasers to do chromatography. Dr. Gale's discussion of form and functionality support my conclusion that the value of the patents-in-suit when considered in a hypothetical negotiation would warrant a reasonable royalty rate no greater than (in contrast to Dr. Gale's discussion of form and functionality support my finding that the value of the patents-in-suit lend themselves to a discussion of form with a lower reasonable royalty rate (in contrast to Mr. Bone's implied royalty rates of up to 14%).
- 140. A lower royalty rate is also consistent with most of the revenue covering the value from the important non-patented element: chromatography and the costs of bringing devices that do chromatography to market.¹⁷⁷

GP #14: The opinion testimony of qualified experts.

141. My opinion regarding the appropriate royalty rate in this matter is based on the Expert Rebuttal Report of Dr. Bruce Gale and the conversations I have had with him.

¹⁷⁶ See Sections IX and X of Gale Rebuttal Report.

¹⁷⁷ *Id*.

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Bio-Rad Expert Report of J.R. Kearl October 21, 2020

move en masse to purchase devices from Cytiva at higher prices rather than from non-infringing alternatives at lower prices, including an improved DuoFlow product that Bio-Rad would have a strong incentive to supply to the market.

156.	With regard to one group of customers,
Ī	
-	
	⁸⁹ In other words, there are
C	customers who are particularly price sensitive and therefore unlikely to purchase Cytiva's
ł	nigh-priced products if low-priced non-infringing substitutes are available. If Bio-Rad's
1	NGC products were to be barred from the market and Cytiva is unable or unwilling to
1	ower its prices sufficient to appeal to the price-sensitive customers that previously
I	purchased Bio-Rad's NGC products, it is likely that Cytiva would both earn no profits
a	among this customer segment and forgo the royalties it could have earned on Bio-Rad's
S	sales of NGC products to these customers. Furthermore, if Cytiva does not market to
I	price-sensitive customers and Bio-Rad cannot sell its NGC products, this price-sensitive
r	market segment would be deprived of an option it now has.

Respectfully submitted this 21st day of October 2020,

James R. Kearl

¹⁸⁹ Deposition of Anna Emilsson, June 25, 2020, pp. 101:4-13.

Exhibit F. Licenses Produced by Bio-Rad and Cytiva

Licensor	Licensee	Effective Date	Licensed Products/Process	License Notes	License Fee	Royalty Rate	Royalty Base and Fee Notes Result of Past Litigation

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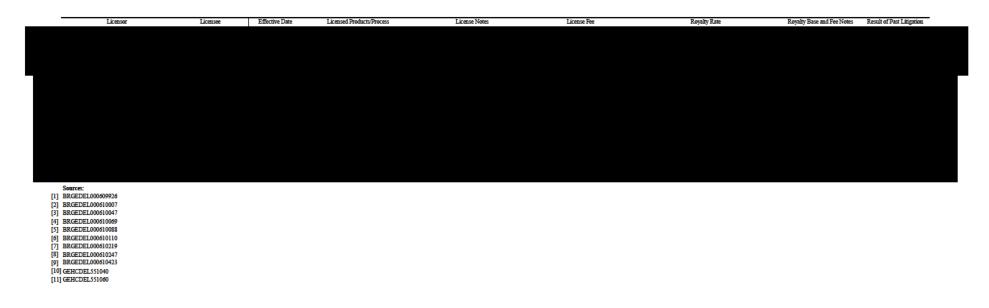


EXHIBIT 11 FILED UNDER SEAL

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           UNITED STATES DISTRICT COURT
                                                              1
                                                                              INDEX TO EXAMINATION
           FOR THE DISTRICT OF DELAWARE
                                                              2
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                                                                     WITNESS: JAMES KEARL, PH.D.
      CYTIVA SWEDEN AB, et al., )
                                                              4
           Plaintiff, )
                                                              5
                                                                     EXAMINATION BY
                                                                                                           PAGE
                  ) Case No. 1:18-CV-
                                                              6
                                                                     Ms. DeWitt
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                  )
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                                                                     Mr. Corredor
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                                                                              JAMES KEARL, PH.D.,
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                                                                        Cytiva Sweden, AB, et al., v. Bio-Rad
                                                             12
                                                                            Laboratories, Incorporated
       HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY
                                                             13
                                                                            Monday, November 23, 2020
        UNDER THE TERMS OF THE PROTECTIVE ORDER
                                                             14
          DEPOSITION OF JAMES KEARL, PH.D.
                                                                           Lori J. Goodin, RPR, CLR, CRR,
             APPEARING REMOTELY
                                                             15
                                                                           RSA, California CSR #13959
           Monday, November 23, 2020
                                                             16
                                                                     KEARL
           9:59 a.m., Mountain Time
                                                             17
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                                                                                 DESCRIPTION
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      Reported by: Lori J. Goodin, RPR, CLR, CRR,
                                                             18
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                                                                     Exhibit 309 Dr. Kearl's Expert Report
            RSA, California CSR #13959
                                                             19
                                                                     Exhibit 310 Errata to Dr. Kearl's report
                                                             20
             DIGITAL EVIDENCE GROUP
                                                                     Exhibit 311 Expert Report of John Bone, CPA 9
            1730 M Street, NW, Suite 812
                                                             21
                                                                     Exhibit 312 Rebuttal Expert Report of
             Washington, D.C. 20036
                                                             22
                                                                            Dr. B. Gale
               (202) 232-0646
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             REMOTE APPEARANCES:
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                                                                               DESCRIPTION
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                                                                    Exhibit 313 Reply report of Mr. Bone
          ARNOLD & PORTER KAYE SCHOLER LLP
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                                                                    Exhibit 314 Microeconomics Theory - Basic 47
          AMY DEWITT, ESQUIRE
                                                                           Principles and Extensions, 11th
          601 Massachusetts Avenue, Northwest
                                                              6
                                                                           Ed., excerpt, BRGEDEL610783
 5
          Washington, D.C. 20001
                                                              7
                                                                    Exhibit 315 Bio-Rad document used in
                                                                                                           56
          202-942-5000
                                                                           Footnote 59 of Dr. Kearl's
 6
          Amy.DeWitt@arnoldporter.com
                                                              8
                                                                           Report, BRGE00006279-301
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                                                                    Exhibit 316 Bio-Rad's 4th Supplemental
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9
                                                                    Exhibit 317 Deposition transcript of
                                                                                                        111
          FELIPE CORREDOR, ESQUIRE
                                                                           P. Chapman
          50 California Street
                                                             12
                                                                    Exhibit 318
10
          22nd Floor
                                                                                    BRGEDEL3000
          San Francisco, California 94111
                                                             13
                                                                    Exhibit 319
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11
          415-875-6600
                                                                           BRGEDEL610435
          Felipecorredor@quinnemanuel.com
                                                             14
                                                                    Exhibit 320
12
                                                                           BRGEDEL610276
13
                                                             15
      ALSO PRESENT:
                                                                                                        172
                                                                    Exhibit 321
14
                                                                           BRGEDEL480859
        Andy Mortensen, Video/Document Technician
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15
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        Candice K. Cornelius, Stout Risius Ross, LLC
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                                                                    Exhibit 323
16
                                                                                     BRGEDEL610423
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                                                                    Exhibit 324
18
                                                                           BRGEDEL610047
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                                                             19
                                                                    Exhibit 325 Adjusted Exhibit D spreadsheet 276
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                                                             20
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                                                             21
                                                                         (All exhibits were provided
22
                                                             22
                                                                         electronically to the reporter.)
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	Page 201	Page	203
1	that answer?	Q. Okay. We will get started and	200
2	MR. CORREDOR: Yes, Dr. Kearl, you	then Dr. Kearl, it is your opinion that if	
3	should feel free to do so.	lost profits are not available, then an	
4	THE WITNESS: Okay, then, Mr. Bone	appropriate royalty rate is percent of net	
5	is correct that I did not, and I should have	sales of accused instruments and modules.	
6	on the sales commission.	6 Correct?	
7	If you do that, it is a tiny amount	7 A. Yes. But the correction that, or	
8	of money; it is a couple hundred thousand	not the not the correction, the additional	
9	dollars.	9 calculations that Felipe will be sending you.	0.0
10	So, that is an error in my	I indicated first thing this morning, you cou	
11	calculation that I own up to and is easily	think of a hypothetical negotiation occurring	
12	corrected.	with an expectation of use dependent on the	
13	BY MS. DEWITT:	number of customers. That is the way I	
14		-	
15	Q. You didn't include it in your	calculated it, if you do that you get to the	
16	errata, did you? A. No, the errata was stuff that is	z percent.	
17		Or Mr. Bone pointed out that you could think of it as a number of customers	
18	just in the report. I have just told you now that it is a small error.		
19		weighted by their expenditures, so your reve	
20	Well, it is a conceptual error that	rina ir you do that; I have recalculated with	,
21	has a small dollar amount attached to it.	consistent with his criticism, and you get a	
22	Q. I believe we talked earlier, Dr.	percent:	
22	Kearl, about getting some updated sales estimates	Q. So, which royalty rate are you	
	D 000	_	
	Page 202	Page	204
1	that you were going to send to Felipe?	offering in this case as the royalty rate that	
1 2		_	
	that you were going to send to Felipe?	offering in this case as the royalty rate that	
2	that you were going to send to Felipe? A. Yes.	offering in this case as the royalty rate that the parties had decided upon at the hypoth	
2	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry,	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation?	etical
2 3 4	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates?	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it	etical
2 3 4 5	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetical	etical
2 3 4 5	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty.	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetica negotiation is set out.	etical 1 ges
2 3 4 5 6	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will send them to him at the next break.	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetica negotiation is set out. But if you take the standard damage expert's position to be the more conservation then you would take the 3.5.	etical 1 ges
2 3 4 5 6 7 8	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetica negotiation is set out. But if you take the standard damage expert's position to be the more conservation.	etical 1 ges
2 3 4 5 6 7 8	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will send them to him at the next break.	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetica negotiation is set out. But if you take the standard damage expert's position to be the more conservation then you would take the 3.5.	etical I ges
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will send them to him at the next break. Felipe do you have them? MR. CORREDOR: No, I do not. MS. DEWITT: Well, I'm about to move into your reasonable royalty analysis, so if they are relevant to your opinions there, maybe we need to take a break now so we can get them. THE WITNESS: Well, I can do this in	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetical negotiation is set out. But if you take the standard damage expert's position to be the more conservative then you would take the 3.5. Q. Okay. Let's stick with your 2 percent rate for the time being since that what your report was centered upon. And one of the bases you rely on to opine that 2 percent is appropriate, is to compare that rate to the range of the royalt rates of the licenses that were produced in case. Correct?	etical l ges ve is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will send them to him at the next break. Felipe do you have them? MR. CORREDOR: No, I do not. MS. DEWITT: Well, I'm about to move into your reasonable royalty analysis, so if they are relevant to your opinions there, maybe we need to take a break now so we can get them. THE WITNESS: Well, I can do this in two seconds, so	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetical negotiation is set out. But if you take the standard damage expert's position to be the more conservative then you would take the 3.5. Q. Okay. Let's stick with your 2 percent rate for the time being since that what your report was centered upon. And one of the bases you rely on the opine that 2 percent is appropriate, is to compare that rate to the range of the royalt rates of the licenses that were produced in case. Correct? A. That is not correct.	etical l ges ve is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will send them to him at the next break. Felipe do you have them? MR. CORREDOR: No, I do not. MS. DEWITT: Well, I'm about to move into your reasonable royalty analysis, so if they are relevant to your opinions there, maybe we need to take a break now so we can get them. THE WITNESS: Well, I can do this in two seconds, so MS. DEWITT: Okay.	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetica negotiation is set out. But if you take the standard damage expert's position to be the more conservative then you would take the 3.5. Q. Okay. Let's stick with your percent rate for the time being since that what your report was centered upon. And one of the bases you rely on to opine that 2 percent is appropriate, is to compare that rate to the range of the royalt rates of the licenses that were produced in case. Correct? A. That is not correct. Q. What is not correct about it?	etical l ges ve is o y this
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	that you were going to send to Felipe? A. Yes. Q. Have you sent those I'm sorry, they were lost profit estimates? MR. CORREDOR: I believe it was royalty. THE WITNESS: Yes, these are reasonable royalty estimates. And I will send them to him at the next break. Felipe do you have them? MR. CORREDOR: No, I do not. MS. DEWITT: Well, I'm about to move into your reasonable royalty analysis, so if they are relevant to your opinions there, maybe we need to take a break now so we can get them. THE WITNESS: Well, I can do this in two seconds, so MS. DEWITT: Okay. THE WITNESS: Okay. I just sent it	offering in this case as the royalty rate that the parties had decided upon at the hypoth negotiation? A. Both are defensible, again it depends on how you think the hypothetical negotiation is set out. But if you take the standard damage expert's position to be the more conservative then you would take the 3.5. Q. Okay. Let's stick with your percent rate for the time being since that what your report was centered upon. And one of the bases you rely on the opine that 2 percent is appropriate, is to compare that rate to the range of the royalt rates of the licenses that were produced in case. Correct? A. That is not correct. Q. What is not correct about it? A. Well, I estimate the 2 percent using the royalt and the standard damage expert's position to be the more conservation.	etical I ges ve is o y this

Page 211 Page 209 1 Q. Is it fair to say that you are using 1 A. It is. And I'm just saying that I 2 2 these licenses as a reasonableness check on your don't think he did it right. Therefore, I don't 3 3 think the percent is, since his methodology is royalty rate vis-à-vis Mr. Bones? 4 4 flawed, then the percent can't be correct A. Yes, just in the sense of if you 5 5 thought about the set of licenses that are listed either. 6 6 there as being more expansive and the license Q. You have your own methodology that 7 7 would come out of the hypothetical negotiation you have proffered in your opinion as to a 8 8 that would be worth more in some sense to the reasonable royalty rate in a hypothetical 9 9 parties than it is surprising that Mr. Bone negotiation? 10 10 believes that the royalty rate would be MR. CORREDOR: Object to form. 11 14 percent. THE WITNESS: No, I have relied 12 When you see the parties sort of 12 primarily on his approach to say if you made 13 13 licensing other important stuff for rates well some adjustments to his approach, what is the 14 14 below 14 percent. reasonable royalty you would get and you will 15 15 Q. If you did not include, if we did get 16 But I also want to make clear that I 16 not have the licenses in Table 4, would you still 17 believe that the percent royalty is reasonable? 17 don't think his approach, methodologically, 18 18 MR. CORREDOR: Object to the form. makes any sense. 19 THE WITNESS: Mine? 19 BY MS. DEWITT: 20 2.0 BY MS. DEWITT: Q. And you did not come up with your 21 21 Q. Yes, your percent reasonable own approach, correct? 22 A. No. royalty rate. Page 212 Page 210 1 MR. CORREDOR: Object to the form. A. No, well if you look at the 2 comparable licenses that Dr. Gale believes are 2 BY MS. DEWITT: 3 3 comparable, then yes, it is in that range which I Q. Okay. You understand that if you 4 think is or something in that want to rely on royalty rate from another license 5 5 agreement that the license you compare must be place. 6 6 both technically and economically comparable, So, relative to what he determines to be comparable licenses, then the royalty rate 7 correct? 8 8 I derive makes sense. A. Correct. 9 9 But I want to be very clear that Q. For example, in Paragraph 117 of 10 10 your report you cite to Mr. Bone's report in his the, I'm using Bone's approach, Mr. Bone's 11 11 approach and Mr. Bone's approach, for reasons I citation from a federal circuit case in the first 12 12 detailed this morning, makes absolutely no sense. sentence, and in the next sentence you state, 13 13 So, I don't think he has a "However licenses even when not informative with 14 methodology or I'm certain that he doesn't have a regard to royalty rates, because they are judged 15 15 methodology that has derived a reasonable royalty not to be comparable, may be informative with 16 16 that would be the outcome of a hypothetical respect to other characteristics of a 17 17 negotiation between parties intent on licensing hypothetical negotiation." 18 18 the technology here. He just has not valued the Do you see that? 19 19 technology. A. Right. 20 20 Q. So, it is your understanding that if O. Did we agree earlier that your 21 21 reasonable royalty rate is derived from the technology is not comparable, then the 2.2 2.2 Mr. Bone's methodology? royalty rate is not informative. Correct?

Page 213 Page 215 1 MR. CORREDOR: Object to form. 1 between these parties, would come along some 2 2 THE WITNESS: Well, it is not a license. 3 3 point estimate of the reasonable royalty that And you looked at the thousand 4 4 would come out of a hypothetical negotiation. licenses and you said these were negotiated along 5 5 I agree to that. and they never negotiated a lump sum license. 6 6 But as I just indicated if you had So, why would I believe that that 7 7 royalties that were no higher than would be the outcome of a hypothetical 8 8 for technologies that are functional and not negotiation. 9 9 just form factors, then you might question a That is a useful insight that 10 10 form factor royalty that is in excess of that economics brings about thinking about the 11 11 by these same parties. hypothetical negotiation. 12 12 Q. Let's go to Table 4. Did you See, it is just a way thinking about 13 13 whether or not 14 percent makes any sense. discuss any of these licenses with Dr. Gale? 14 14 But that is not directly why I used A. Did I --15 15 these, or, the point of this sentence is, Q. Discuss any of these licenses with 16 16 that even if the law says you have to have a Dr. Gale. 17 very close match in order to use the royalty 17 A. I discussed the two that he judged 18 18 in one for the royalty for the other, that to be comparable. 19 19 doesn't mean that you can't get good Q. If you could not rely on any of the 2.0 20 licenses from Table 4, would you still believe information from the types and the structure 21 21 your percent or your percent, and the form of the licenses about how the 22 2.2 hypothetical negotiation would unfold. percent reasonable royalty rate would be Page 216 Page 214 1 1 BY MS. DEWITT: reasonable? 2 2 MR. CORREDOR: Object to form. Q. The last sentence of Paragraph 117 3 3 you write, "These characteristics include THE WITNESS: Well a good answer to features such as type of royalty, exclusivity, that is in the negative which is, in my --5 5 regions in which the licenses can be practiced, My opinion in this matter is that 6 6 the presence or absence of field of use Mr. Bone does not have a methodology that restrictions." 7 reliably estimates a reasonable royalty. So 8 8 that his reasonable royalty estimates make Do you have a particular source for 9 9 that understanding? little sense. 10 A. No, this is just how licensing 10 But even if you took them for what 11 11 people would think about licenses, and, economic they were, you accepted everything that he 12 experts would think about licenses, which is they 12 assumed, and all of the mistakes he made 13 13 tell you something about how people undertake and that, and you corrected for some very simple 14 14 think about licensing. adjustments, that you would not have royalty 15 15 So, let me give you an example. I rates between 9 and 14 percent but you would 16 16 did a case a number of years ago that had 1,000 have a royalty rate that was much lower in 17 17 the to and a half percent range. licenses in it that had been disclosed by both 18 18 BY MS. DEWITT: sides. There was, there was not a single lump 19 19 sum license in the thousands, they were all Q. If you could not rely on any of the 20 20 running royalties. license agreements in Table 4 would you have any

54 (Pages 213 to 216)

basis to say that Mr. Bones implied 14 percent

royalty rate is unreasonable based on a

The expert on the other side had

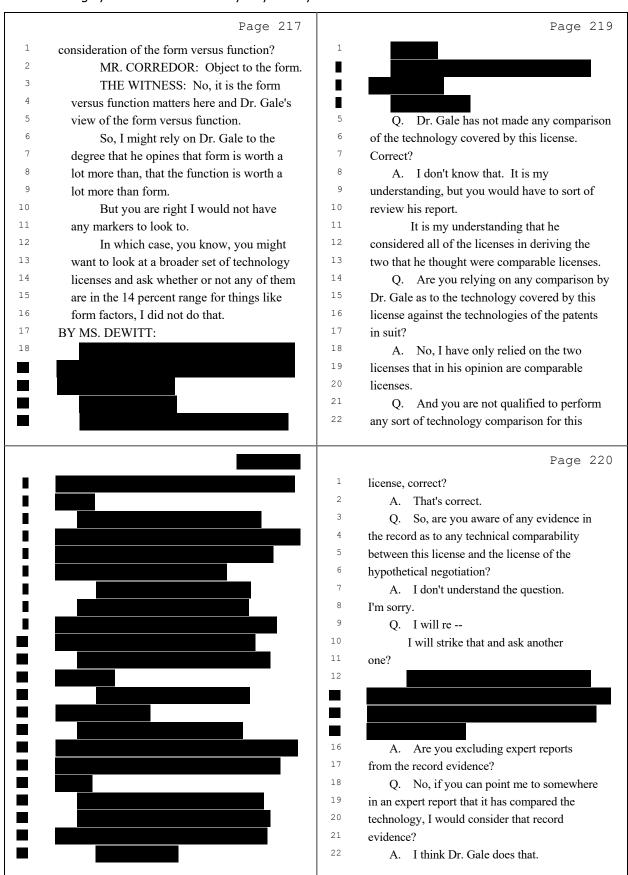
argued that out of the hypothetical negotiation

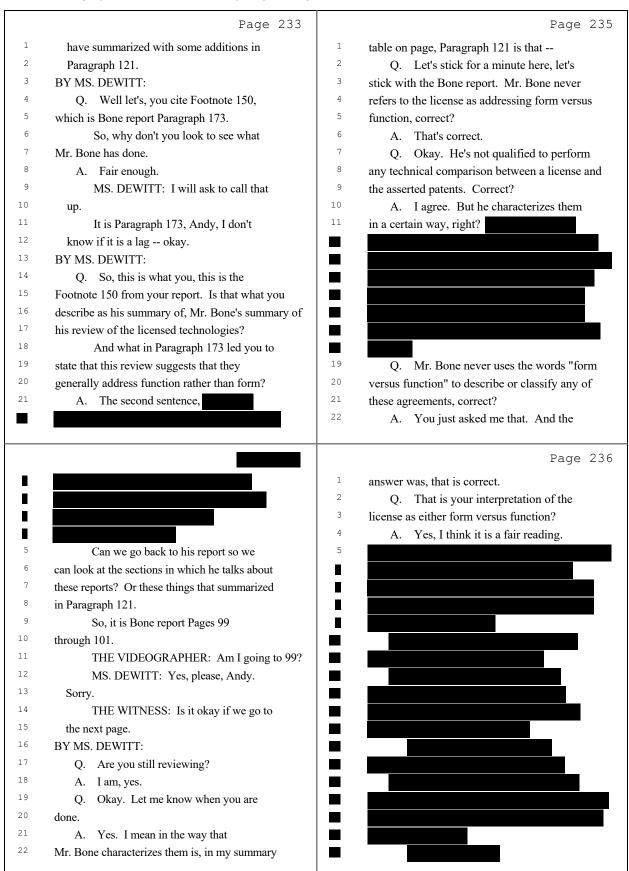
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Page 301 Page 303 1 sections of the, of Dr. Gale's rebuttal report? 1 Paragraph 143. 2 2 A. Correct. Well, I don't know the A. Yes. 3 3 MR. CORREDOR: Could we pull that paragraph. I know it is at the end of the 4 4 up, Exhibit 312? And I want to go to report, so ... 5 5 Paragraph 306 which is at the bottom of Q. Right. Is it your opinion that 6 6 Page 91, running onto the next page. these licenses are consistent with a reasonable 7 7 BY MR. CORREDOR: royalty of 2 percent? 8 8 Q. Do you recognize these pages as the A. Yes. 9 9 pages relating to the non-infringing alternative Q. Okay. That is all I have, 10 10 that we have been discussing? Dr. Kearl, thank you. 11 A. Yes. MS. DEWITT: No additional questions 12 12 And do you see the last sentence in on my end. 13 13 Paragraph 306 that says. THE VIDEOGRAPHER: All right. Is 14 there anything else we need to do before we 15 go off the record? No? All right. 16 Yes. MS. DEWITT: Not on my end. A. 17 17 THE VIDEOGRAPHER: The time is Does that support your opinion that 18 18 customers don't care about what is under the 5:08 p.m. and this concludes today's video 19 19 hood? deposition of James Kearl. 2.0 2.0 MS. DEWITT: Object to form. (Whereupon, signature not having been 21 THE WITNESS: Yes, the, I mean this waived, the deposition ended at 5:08 p.m.) 22 is a technical opinion, and I have no opinion Page 302 Page 304 CERTIFICATE OF COURT REPORTER about the technical opinion. I, LORI J. GOODIN, RPR, CLR, CRR, 2 But it is, it doesn't matter how you CA CSR # 13959, the reporter before whom the foregoing deposition was taken, do hereby certify accomplish the task as long as it is that the witness whose testimony appears in the accomplished in a way that is not interfering foregoing deposition was sworn by me; that the testimony of said witness was taken by me in 5 with what you really want to do, then you machine shorthand and thereafter transcribed by computer-aided transcription; that said 6 shouldn't care particularly what is under the deposition is a true record of the testimony 7 given by said witness; that I am neither counsel hood. for, related to, nor employed by any of the 8 Q. Great. That is all I had for this parties to the action in which this deposition was taken; and, further, that I am not a relative or 9 one. And then I have a couple of questions. employee of any attorney or counsel employed by 10 MR. CORREDOR: We can close out of the parties hereto, or financially or otherwise interested in the outcome of this action. 11 this report. 10 11 12 BY MR. CORREDOR: 12 13 LORI J. GOODIN, RPR, CLR, CRR 13 Q. And do you also remember testifying 14 Notary Public in and for: 14 about two comparable licenses you relied upon? STATE OF FLORIDA, COUNTY OF SARASOTA Notary Commission Number: GG987804 15 A. Yes. 16 My Commission expires: May 12, 2024 16 STATE OF CALIFORNIA, CA CSR# 13959 MS. DEWITT: Object to form. 17 My Commission expires: February 22, 2021 17 BY MR. CORREDOR: STATE OF MARYLAND, COUNTY OF ANNE ARUNDEL 18 My Commission expires: August 2, 2021 18 Q. And those two licenses were the DISTRICT OF COLUMBIA, WASHINGTON DC 19 19 My Commission expires: May 14, 2021 licenses? COMMONWEALTH OF VIRGINIA, COUNTY OF FAIRFAX 20 Yes. A. 2.0 My Commission expires: February 28, 2022 STATE OF DELAWARE: COUNTY OF KENT 21 And that you relied on those 21 My Commission expires: October 9, 2021 22 STATE OF PENNSYLVANIA, COUNTY OF LEHIGH licenses in Section 8 of your report starting at My Commission expires: April 5, 2021

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11/23/2020 Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc. James Kearl, Ph.D. Highly Confidential - Attorneys' Eyes Only - Under the Terms of the Protective Order

	Page 305	Page 307
1	James Kearl, Ph.D., c/o	Digital Evidence Group, LLC
_	QUINN EMANUEL URQUHART & SULLIVAN, LLP	Digital Evidence Group, EEC
2	50 California Street, 22nd Floor	1750 111 54 664, 1777, 5416 612
	San Francisco, California 94111	Washington, D.C. 20036
3	Sair Faireisco, Carrotina 7 1717	4 (202)232-0646
4	Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.	5
	Date of deposition: November 23, 2020	6 ERRATA SHEET
5	Deponent: James Kearl, Ph.D.	7
6	1	
7	Please be advised that the transcript in the above	8 Case: Cytiva Sweden AB, et al. v. Bio-Rad Laboratories, Inc.
8	referenced matter is now complete and ready for signature.	9 Witness Name: James Kearl, Ph.D.
9	The deponent may come to this office to sign the transcript,	Deposition Date: November 23, 2020
10	a copy may be purchased for the witness to review and sign,	Page No. Line No. Change
11	or the deponent and/or counsel may waive the option of	12
12	signing. Please advise us of the option selected.	
13	Please forward the errata sheet and the original signed	13
14	signature page to counsel noticing the deposition, noting the	14
15	applicable time period allowed for such by the governing	15
16	Rules of Procedure. If you have any questions, please do	16
17	not hesitate to call our office at (202)-232-0646.	17
18		
19	a	18
20	Sincerely,	19
21	Digital Evidence Group	20
21	Copyright 2020 Digital Evidence Group	21
22	Copying is forbidden, including electronically, absent	22 Signature Date
22	express written consent.	Signature Date
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1	Page 306 Digital Evidence Group, L.L.C. 1730 M Street, NW, Suite 812	
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2	Digital Evidence Group, L.L.C. 1730 M Street, NW, Suite 812 Washington, D.C. 20036 (202) 232-0646 SIGNATURE PAGE	
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